表 2.7.4.7-付録-17　有害事象の程度別発現頻度（232 試験）（59/68）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=138)	 1 mg (N=134)	 2 mg (N=132)
呼吸器、胸郭および縦隔障害（続き）				
息詰まり	Overall	-	-	1(0.8)
	Mild	-	-	1(0.8)
	Moderate	-	-	-
	Severe	-	-	-
咽喉乾燥	Overall	-	1(0.7)	-
	Mild	-	1(0.7)	-
	Moderate	-	-	-
	Severe	-	-	-
鼻出血	Overall	1(0.7)	-	-
	Mild	1(0.7)	-	-
	Moderate	-	-	-
	Severe	-	-	-
胸膜炎	Overall	-	1(0.7)	-
	Mild	-	1(0.7)	-
	Moderate	-	-	-
	Severe	-	-	-
胸膜痛	Overall	-	1(0.7)	-
	Mild	-	1(0.7)	-
	Moderate	-	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.3.1.5

表 2.7.4.7-付録-17　有害事象の程度別発現頻度（232 試験）（60/68）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=138)	 1 mg (N=134)	 2 mg (N=132)
呼吸器、胸郭および縦隔障害（続き）				
呼吸窮迫	Overall	1(0.7)	-	-
	Mild	-	-	-
	Moderate	1(0.7)	-	-
	Severe	-	-	-
喘鳴	Overall	-	1(0.7)	-
	Mild	-	-	-
	Moderate	-	1(0.7)	-
	Severe	-	-	-
皮膚および皮下組織障害	Overall	10(7.2)	11(8.2)	8(6.1)
	Mild	8(5.8)	6(4.5)	5(3.8)
	Moderate	2(1.4)	5(3.7)	3(2.3)
	Severe	-	-	-
発疹	Overall	2(1.4)	2(1.5)	3(2.3)
	Mild	1(0.7)	2(1.5)	3(2.3)
	Moderate	1(0.7)	-	-
	Severe	-	-	-
脱毛症	Overall	1(0.7)	1(0.7)	2(1.5)
	Mild	1(0.7)	1(0.7)	-
	Moderate	-	-	2(1.5)
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.3.1.5

表 2.7.4.7-付録-17　有害事象の程度別発現頻度（232 試験）（61/68）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=138)	 1 mg (N=134)	 2 mg (N=132)
皮膚および皮下組織障害（続き）				
接触性皮膚炎	Overall	-	2(1.5)	1(0.8)
	Mild	-	1(0.7)	-
	Moderate	-	1(0.7)	1(0.8)
	Severe	-	-	-
皮膚病変	Overall	3(2.2)	-	-
	Mild	3(2.2)	-	-
	Moderate	-	-	-
	Severe	-	-	-
多汗症	Overall	1(0.7)	1(0.7)	-
	Mild	-	-	-
	Moderate	1(0.7)	1(0.7)	-
	Severe	-	-	-
そう痒症	Overall	1(0.7)	1(0.7)	-
	Mild	1(0.7)	-	-
	Moderate	-	1(0.7)	-
	Severe	-	-	-
円形脱毛症	Overall	-	1(0.7)	-
	Mild	-	1(0.7)	-
	Moderate	-	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]. Statistical Analysis Report (5.3.5.3-1) Table 2.3.1.5

表 2.7.4.7-付録-17　有害事象の程度別発現頻度（232 試験）（62/68）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=138)	 1 mg (N=134)	 2 mg (N=132)
皮膚および皮下組織障害（続き）				
皮膚炎	Overall	-	1(0.7)	-
	Mild	-	1(0.7)	-
	Moderate	-	-	-
	Severe	-	-	-
薬疹	Overall	-	1(0.7)	-
	Mild	-	1(0.7)	-
	Moderate	-	-	-
	Severe	-	-	-
皮膚乾燥	Overall	-	1(0.7)	-
	Mild	-	1(0.7)	-
	Moderate	-	-	-
	Severe	-	-	-
過角化	Overall	-	1(0.7)	-
	Mild	-	1(0.7)	-
	Moderate	-	-	-
	Severe	-	-	-
寝汗	Overall	1(0.7)	-	-
	Mild	1(0.7)	-	-
	Moderate	-	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.3.1.5

表 2.7.4.7-付録-17　有害事象の程度別発現頻度（232 試験）（63/68）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=138)	 1 mg (N=134)	 2 mg (N=132)
皮膚および皮下組織障害（続き）				
丘疹	Overall	-	-	1(0.8)
	Mild	-	-	1(0.8)
	Moderate	-	-	-
	Severe	-	-	-
類天疱瘡	Overall	-	1(0.7)	-
	Mild	-	-	-
	Moderate	-	1(0.7)	-
	Severe	-	-	-
紅斑性皮疹	Overall	-	-	1(0.8)
	Mild	-	-	1(0.8)
	Moderate	-	-	-
	Severe	-	-	-
斑状丘疹状皮疹	Overall	1(0.7)	-	-
	Mild	1(0.7)	-	-
	Moderate	-	-	-
	Severe	-	-	-
皮膚変色	Overall	-	1(0.7)	-
	Mild	-	1(0.7)	-
	Moderate	-	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.3.1.5

表 2.7.4.7-付録-17　有害事象の程度別発現頻度（232 試験）（64/68）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=138)	 1 mg (N=134)	 2 mg (N=132)
皮膚および皮下組織障害（続き）				
皮膚剥脱	Overall	1(0.7)	-	-
	Mild	1(0.7)	-	-
	Moderate	-	-	-
	Severe	-	-	-
蕁麻疹	Overall	-	1(0.7)	-
	Mild	-	-	-
	Moderate	-	1(0.7)	-
	Severe	-	-	-
社会環境	Overall	-	1(0.7)	-
	Mild	-	1(0.7)	-
	Moderate	-	-	-
	Severe	-	-	-
就労能力障害者	Overall	-	1(0.7)	-
	Mild	-	1(0.7)	-
	Moderate	-	-	-
	Severe	-	-	-
外科および内科処置	Overall	4(2.9)	4(3.0)	4(3.0)
	Mild	1(0.7)	3(2.2)	3(2.3)
	Moderate	2(1.4)	1(0.7)	1(0.8)
	Severe	1(0.7)	-	-

有害事象名：MedDRA/J ver[redacted]. Statistical Analysis Report (5.3.5.3-1) Table 2.3.1.5

表 2.7.4.7-付録-17　有害事象の程度別発現頻度（232 試験）（65/68）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=138)	 1 mg (N=134)	 2 mg (N=132)
外科および内科処置（続き）				
白内障手術	Overall	2(1.4)	1(0.7)	2(1.5)
	Mild	1(0.7)	-	1(0.8)
	Moderate	1(0.7)	1(0.7)	1(0.8)
	Severe	-	-	-
皮膚新生物切除	Overall	-	1(0.7)	1(0.8)
	Mild	-	1(0.7)	1(0.8)
	Moderate	-	-	-
	Severe	-	-	-
胆石摘出	Overall	1(0.7)	-	-
	Mild	-	-	-
	Moderate	-	-	-
	Severe	1(0.7)	-	-
デブリードマン	Overall	-	1(0.7)	-
	Mild	-	1(0.7)	-
	Moderate	-	-	-
	Severe	-	-	-
歯肉手術	Overall	-	-	1(0.8)
	Mild	-	-	1(0.8)
	Moderate	-	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.3.1.5

表 2.7.4.7-付録-17　有害事象の程度別発現頻度（232 試験）（66/68）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=138)	 1 mg (N=134)	 2 mg (N=132)
外科および内科処置（続き）				
色素性母斑切除	Overall	1(0.7)	-	-
	Mild	-	-	-
	Moderate	1(0.7)	-	-
	Severe	-	-	-
瘢痕切除	Overall	-	1(0.7)	-
	Mild	-	1(0.7)	-
	Moderate	-	-	-
	Severe	-	-	-
縫合	Overall	-	1(0.7)	-
	Mild	-	1(0.7)	-
	Moderate	-	-	-
	Severe	-	-	-
血管障害	Overall	13(9.4)	5(3.7)	8(6.1)
	Mild	6(4.3)	3(2.2)	3(2.3)
	Moderate	6(4.3)	1(0.7)	5(3.8)
	Severe	1(0.7)	1(0.7)	-
起立性低血圧	Overall	5(3.6)	1(0.7)	3(2.3)
	Mild	3(2.2)	1(0.7)	-
	Moderate	2(1.4)	-	3(2.3)
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.3.1.5

表 2.7.4.7-付録-17　有害事象の程度別発現頻度（232 試験）（67/68）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=138)	 1 mg (N=134)	 2 mg (N=132)
血管障害（続き）				
高血圧	Overall	5(3.6)	2(1.5)	1(0.8)
	Mild	2(1.4)	1(0.7)	-
	Moderate	2(1.4)	1(0.7)	1(0.8)
	Severe	1(0.7)	-	-
潮紅	Overall	1(0.7)	-	1(0.8)
	Mild	-	-	1(0.8)
	Moderate	1(0.7)	-	-
	Severe	-	-	-
静脈瘤	Overall	1(0.7)	-	1(0.8)
	Mild	1(0.7)	-	-
	Moderate	-	-	1(0.8)
	Severe	-	-	-
大動脈瘤	Overall	-	1(0.7)	-
	Mild	-	-	-
	Moderate	-	-	-
	Severe	-	1(0.7)	-
血腫	Overall	-	-	1(0.8)
	Mild	-	-	1(0.8)
	Moderate	-	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]　Statistical Analysis Report (5.3.5.3-1) Table 2.3.1.5

表 2.7.4.7-付録-17　有害事象の程度別発現頻度（232 試験）（68/68）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=138)	 1 mg (N=134)	 2 mg (N=132)
血管障害（続き）				
ほてり	Overall	-	-	1(0.8)
	Mild	-	-	1(0.8)
	Moderate	-	-	-
	Severe	-	-	-
低血圧	Overall	1(0.7)	-	-
	Mild	-	-	-
	Moderate	1(0.7)	-	-
	Severe	-	-	-
起立性高血圧	Overall	1(0.7)	-	-
	Mild	1(0.7)	-	-
	Moderate	-	-	-
	Severe	-	-	-
末梢動脈閉塞性疾患	Overall	-	1(0.7)	-
	Mild	-	1(0.7)	-
	Moderate	-	-	-
	Severe	-	-	-
血栓症	Overall	-	1(0.7)	-
	Mild	-	-	-
	Moderate	-	-	-
	Severe	-	1(0.7)	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.3.1.5

表 2.7.4.7-付録-18　有害事象の程度別発現頻度（CCT-002 試験）（1/44）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=141)	 0.5 mg (N=133)	 1 mg (N=129)
Subjects with Any TEAEs	Overall	71(50.4)	93(69.9)	95(73.6)
	Mild	55(39.0)	65(48.9)	62(48.1)
	Moderate	12(8.5)	26(19.5)	30(23.3)
	Severe	4(2.8)	2(1.5)	3(2.3)
血液およびリンパ系障害	Overall	-	1(0.8)	-
	Mild	-	1(0.8)	-
	Moderate	-	-	-
	Severe	-	-	-
貧血	Overall	-	1(0.8)	-
	Mild	-	1(0.8)	-
	Moderate	-	-	-
	Severe	-	-	-
心臓障害	Overall	3(2.1)	-	4(3.1)
	Mild	1(0.7)	-	2(1.6)
	Moderate	1(0.7)	-	1(0.8)
	Severe	1(0.7)	-	1(0.8)
狭心症	Overall	-	-	1(0.8)
	Mild	-	-	-
	Moderate	-	-	1(0.8)
	Severe	-	-	-
うっ血性心不全	Overall	1(0.7)	-	-
	Mild	-	-	-
	Moderate	-	-	-
	Severe	1(0.7)	-	-

有害事象名：MedDRA/J ver[redacted]. Statistical Analysis Report (5.3.5.1-3) Table 4.1.1.5

表 2.7.4.7-付録-18　有害事象の程度別発現頻度（CCT-002 試験）（2/44）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=141)	 0.5 mg (N=133)	 1 mg (N=129)
心臓障害（続き）				
心筋虚血	Overall	1(0.7)	-	-
	Mild	-	-	-
	Moderate	1(0.7)	-	-
	Severe	-	-	-
動悸	Overall	1(0.7)	-	-
	Mild	1(0.7)	-	-
	Moderate	-	-	-
	Severe	-	-	-
洞性徐脈	Overall	-	-	1(0.8)
	Mild	-	-	1(0.8)
	Moderate	-	-	-
	Severe	-	-	-
ストレス心筋症	Overall	-	-	1(0.8)
	Mild	-	-	-
	Moderate	-	-	-
	Severe	-	-	1(0.8)
頻脈	Overall	-	-	1(0.8)
	Mild	-	-	1(0.8)
	Moderate	-	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.1-3) Table 4.1.1.5

表 2.7.4.7-付録-18　有害事象の程度別発現頻度（CCT-002 試験）（3/44）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=141)	 0.5 mg (N=133)	 1 mg (N=129)
耳および迷路障害	Overall	1(0.7)	1(0.8)	-
	Mild	1(0.7)	1(0.8)	-
	Moderate	-	-	-
	Severe	-	-	-
耳痛	Overall	1(0.7)	-	-
	Mild	1(0.7)	-	-
	Moderate	-	-	-
	Severe	-	-	-
回転性めまい	Overall	-	1(0.8)	-
	Mild	-	1(0.8)	-
	Moderate	-	-	-
	Severe	-	-	-
眼障害	Overall	-	2(1.5)	3(2.3)
	Mild	-	2(1.5)	3(2.3)
	Moderate	-	-	-
	Severe	-	-	-
眼瞼炎	Overall	-	-	1(0.8)
	Mild	-	-	1(0.8)
	Moderate	-	-	-
	Severe	-	-	-
結膜出血	Overall	-	1(0.8)	-
	Mild	-	1(0.8)	-
	Moderate	-	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.1-3) Table 4.1.1.5

表 2.7.4.7-付録-18　有害事象の程度別発現頻度（CCT-002 試験）（4/44）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=141)	 0.5 mg (N=133)	 1 mg (N=129)
眼障害（続き）				
眼乾燥	Overall	-	-	1(0.8)
	Mild	-	-	1(0.8)
	Moderate	-	-	-
	Severe	-	-	-
眼脂	Overall	-	1(0.8)	-
	Mild	-	1(0.8)	-
	Moderate	-	-	-
	Severe	-	-	-
緑内障	Overall	-	-	1(0.8)
	Mild	-	-	1(0.8)
	Moderate	-	-	-
	Severe	-	-	-
胃腸障害	Overall	16(11.3)	14(10.5)	19(14.7)
	Mild	14(9.9)	12(9.0)	15(11.6)
	Moderate	2(1.4)	2(1.5)	4(3.1)
	Severe	-	-	-
悪心	Overall	1(0.7)	4(3.0)	4(3.1)
	Mild	1(0.7)	3(2.3)	4(3.1)
	Moderate	-	1(0.8)	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]. Statistical Analysis Report (5.3.5.1-3) Table 4.1.1.5

表 2.7.4.7-付録-18　有害事象の程度別発現頻度（CCT-002 試験）（5/44）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=141)	 0.5 mg (N=133)	 1 mg (N=129)
胃腸障害（続き）				
便秘	Overall	3(2.1)	2(1.5)	2(1.6)
	Mild	2(1.4)	2(1.5)	2(1.6)
	Moderate	1(0.7)	-	-
	Severe	-	-	-
齲歯	Overall	5(3.5)	1(0.8)	-
	Mild	4(2.8)	1(0.8)	-
	Moderate	1(0.7)	-	-
	Severe	-	-	-
嘔吐	Overall	1(0.7)	2(1.5)	3(2.3)
	Mild	1(0.7)	2(1.5)	1(0.8)
	Moderate	-	-	2(1.6)
	Severe	-	-	-
消化不良	Overall	2(1.4)	1(0.8)	1(0.8)
	Mild	2(1.4)	1(0.8)	1(0.8)
	Moderate	-	-	-
	Severe	-	-	-
腹部不快感	Overall	1(0.7)	-	1(0.8)
	Mild	1(0.7)	-	1(0.8)
	Moderate	-	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.1-3) Table 4.1.1.5

表 2.7.4.7-付録-18　有害事象の程度別発現頻度（CCT-002 試験）（6/44）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=141)	 0.5 mg (N=133)	 1 mg (N=129)
胃腸障害（続き）				
腹部膨満	Overall	-	1(0.8)	1(0.8)
	Mild	-	1(0.8)	1(0.8)
	Moderate	-	-	-
	Severe	-	-	-
下痢	Overall	-	1(0.8)	1(0.8)
	Mild	-	1(0.8)	1(0.8)
	Moderate	-	-	-
	Severe	-	-	-
胃炎	Overall	-	1(0.8)	1(0.8)
	Mild	-	1(0.8)	-
	Moderate	-	-	1(0.8)
	Severe	-	-	-
胃食道逆流性疾患	Overall	-	1(0.8)	1(0.8)
	Mild	-	-	-
	Moderate	-	1(0.8)	1(0.8)
	Severe	-	-	-
腹痛	Overall	1(0.7)	-	-
	Mild	1(0.7)	-	-
	Moderate	-	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.1-3) Table 4.1.1.5

表 2.7.4.7-付録-18　有害事象の程度別発現頻度（CCT-002 試験）（7/44）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=141)	 0.5 mg (N=133)	 1 mg (N=129)
胃腸障害（続き）				
肛門出血	Overall	1(0.7)	-	-
	Mild	1(0.7)	-	-
	Moderate	-	-	-
	Severe	-	-	-
アフタ性潰瘍	Overall	-	-	1(0.8)
	Mild	-	-	1(0.8)
	Moderate	-	-	-
	Severe	-	-	-
小腸炎	Overall	-	-	1(0.8)
	Mild	-	-	-
	Moderate	-	-	1(0.8)
	Severe	-	-	-
腸炎	Overall	-	-	1(0.8)
	Mild	-	-	1(0.8)
	Moderate	-	-	-
	Severe	-	-	-
舌炎	Overall	-	-	1(0.8)
	Mild	-	-	1(0.8)
	Moderate	-	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]　Statistical Analysis Report (5.3.5.1-3) Table 4.1.1.5

表 2.7.4.7-付録-18　有害事象の程度別発現頻度（CCT-002 試験）（8/44）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=141)	 0.5 mg (N=133)	 1 mg (N=129)
胃腸障害（続き）				
口唇腫脹	Overall	1(0.7)	-	-
	Mild	1(0.7)	-	-
	Moderate	-	-	-
	Severe	-	-	-
不正咬合	Overall	-	1(0.8)	-
	Mild	-	1(0.8)	-
	Moderate	-	-	-
	Severe	-	-	-
口腔知覚不全	Overall	1(0.7)	-	-
	Mild	1(0.7)	-	-
	Moderate	-	-	-
	Severe	-	-	-
流涎過多	Overall	1(0.7)	-	-
	Mild	1(0.7)	-	-
	Moderate	-	-	-
	Severe	-	-	-
口内炎	Overall	-	-	1(0.8)
	Mild	-	-	1(0.8)
	Moderate	-	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]　Statistical Analysis Report (5.3.5.1-3) Table 4.1.1.5

表 2.7.4.7-付録-18　有害事象の程度別発現頻度（CCT-002 試験）（9/44）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=141)	 0.5 mg (N=133)	 1 mg (N=129)
一般・全身障害および投与部位の状態	Overall	5(3.5)	3(2.3)	4(3.1)
	Mild	4(2.8)	2(1.5)	4(3.1)
	Moderate	1(0.7)	1(0.8)	-
	Severe	-	-	-
末梢性浮腫	Overall	4(2.8)	1(0.8)	-
	Mild	3(2.1)	1(0.8)	-
	Moderate	1(0.7)	-	-
	Severe	-	-	-
胸痛	Overall	1(0.7)	1(0.8)	-
	Mild	1(0.7)	1(0.8)	-
	Moderate	-	-	-
	Severe	-	-	-
胸部不快感	Overall	-	-	1(0.8)
	Mild	-	-	1(0.8)
	Moderate	-	-	-
	Severe	-	-	-
不快感	Overall	-	-	1(0.8)
	Mild	-	-	1(0.8)
	Moderate	-	-	-
	Severe	-	-	-
廃用症候群	Overall	-	1(0.8)	-
	Mild	-	-	-
	Moderate	-	1(0.8)	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.1-3) Table 4.1.1.5

表 2.7.4.7-付録-18　有害事象の程度別発現頻度（CCT-002 試験）（10/44）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=141)	 0.5 mg (N=133)	 1 mg (N=129)
一般・全身障害および投与部位の状態（続き）				
浮腫	Overall	-	-	1(0.8)
	Mild	-	-	1(0.8)
	Moderate	-	-	-
	Severe	-	-	-
口渇	Overall	-	-	1(0.8)
	Mild	-	-	1(0.8)
	Moderate	-	-	-
	Severe	-	-	-
肝胆道系障害	Overall	1(0.7)	4(3.0)	1(0.8)
	Mild	1(0.7)	3(2.3)	1(0.8)
	Moderate	-	1(0.8)	-
	Severe	-	-	-
肝機能異常	Overall	-	3(2.3)	-
	Mild	-	2(1.5)	-
	Moderate	-	1(0.8)	-
	Severe	-	-	-
肝障害	Overall	-	1(0.8)	1(0.8)
	Mild	-	1(0.8)	1(0.8)
	Moderate	-	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.1-3) Table 4.1.1.5

表 2.7.4.7-付録-18　有害事象の程度別発現頻度（CCT-002 試験）（11/44）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=141)	 0.5 mg (N=133)	 1 mg (N=129)
肝胆道系障害（続き）				
胆石症	Overall	1(0.7)	-	-
	Mild	1(0.7)	-	-
	Moderate	-	-	-
	Severe	-	-	-
免疫系障害	Overall	1(0.7)	-	-
	Mild	1(0.7)	-	-
	Moderate	-	-	-
	Severe	-	-	-
季節性アレルギー	Overall	1(0.7)	-	-
	Mild	1(0.7)	-	-
	Moderate	-	-	-
	Severe	-	-	-
感染症および寄生虫症	Overall	23(16.3)	40(30.1)	30(23.3)
	Mild	19(13.5)	38(28.6)	27(20.9)
	Moderate	4(2.8)	2(1.5)	2(1.6)
	Severe	-	-	1(0.8)
鼻咽頭炎	Overall	13(9.2)	24(18.0)	19(14.7)
	Mild	13(9.2)	24(18.0)	19(14.7)
	Moderate	-	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.1-3) Table 4.1.1.5

表 2.7.4.7-付録-18　有害事象の程度別発現頻度（CCT-002 試験）（12/44）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=141)	 0.5 mg (N=133)	 1 mg (N=129)
感染症および寄生虫症（続き）				
結膜炎	Overall	3(2.1)	2(1.5)	2(1.6)
	Mild	3(2.1)	2(1.5)	2(1.6)
	Moderate	-	-	-
	Severe	-	-	-
咽頭炎	Overall	3(2.1)	2(1.5)	-
	Mild	3(2.1)	2(1.5)	-
	Moderate	-	-	-
	Severe	-	-	-
気管支炎	Overall	1(0.7)	-	3(2.3)
	Mild	-	-	2(1.6)
	Moderate	1(0.7)	-	1(0.8)
	Severe	-	-	-
膀胱炎	Overall	1(0.7)	2(1.5)	1(0.8)
	Mild	1(0.7)	2(1.5)	1(0.8)
	Moderate	-	-	-
	Severe	-	-	-
足部白癬	Overall	-	2(1.5)	2(1.6)
	Mild	-	2(1.5)	2(1.6)
	Moderate	-	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]. Statistical Analysis Report (5.3.5.1-3) Table 4.1.1.5

表 2.7.4.7-付録-18　有害事象の程度別発現頻度（CCT-002 試験）（13/44）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=141)	 0.5 mg (N=133)	 1 mg (N=129)
感染症および寄生虫症（続き）				
蜂巣炎	Overall	1(0.7)	-	2(1.6)
	Mild	-	-	1(0.8)
	Moderate	1(0.7)	-	1(0.8)
	Severe	-	-	-
インフルエンザ	Overall	1(0.7)	1(0.8)	1(0.8)
	Mild	1(0.7)	1(0.8)	-
	Moderate	-	-	1(0.8)
	Severe	-	-	-
胃腸炎	Overall	-	1(0.8)	1(0.8)
	Mild	-	1(0.8)	1(0.8)
	Moderate	-	-	-
	Severe	-	-	-
帯状疱疹	Overall	2(1.4)	-	-
	Mild	-	-	-
	Moderate	2(1.4)	-	-
	Severe	-	-	-
尿路感染	Overall	1(0.7)	1(0.8)	-
	Mild	1(0.7)	1(0.8)	-
	Moderate	-	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]. Statistical Analysis Report (5.3.5.1-3) Table 4.1.1.5

表 2.7.4.7-付録-18　有害事象の程度別発現頻度（CCT-002 試験）（14/44）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=141)	 0.5 mg (N=133)	 1 mg (N=129)
感染症および寄生虫症（続き）				
虫垂炎	Overall	-	1(0.8)	-
	Mild	-	-	-
	Moderate	-	1(0.8)	-
	Severe	-	-	-
細菌性膣症	Overall	-	1(0.8)	-
	Mild	-	1(0.8)	-
	Moderate	-	-	-
	Severe	-	-	-
皮膚真菌感染	Overall	-	1(0.8)	-
	Mild	-	1(0.8)	-
	Moderate	-	-	-
	Severe	-	-	-
歯肉炎	Overall	-	-	1(0.8)
	Mild	-	-	1(0.8)
	Moderate	-	-	-
	Severe	-	-	-
単純ヘルペス	Overall	-	1(0.8)	-
	Mild	-	1(0.8)	-
	Moderate	-	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]. Statistical Analysis Report (5.3.5.1-3) Table 4.1.1.5

表 2.7.4.7-付録-18　有害事象の程度別発現頻度（CCT-002 試験）（15/44）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=141)	 0.5 mg (N=133)	 1 mg (N=129)
感染症および寄生虫症（続き）				
感染性脊椎炎	Overall	-	-	1(0.8)
	Mild	-	-	-
	Moderate	-	-	-
	Severe	-	-	1(0.8)
口腔カンジダ症	Overall	-	-	1(0.8)
	Mild	-	-	1(0.8)
	Moderate	-	-	-
	Severe	-	-	-
口腔ヘルペス	Overall	-	-	1(0.8)
	Mild	-	-	1(0.8)
	Moderate	-	-	-
	Severe	-	-	-
中耳炎	Overall	-	1(0.8)	-
	Mild	-	1(0.8)	-
	Moderate	-	-	-
	Severe	-	-	-
歯周炎	Overall	-	1(0.8)	-
	Mild	-	1(0.8)	-
	Moderate	-	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.1-3) Table 4.1.1.5

表 2.7.4.7-付録-18　有害事象の程度別発現頻度（CCT-002 試験）（16/44）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=141)	 0.5 mg (N=133)	 1 mg (N=129)
感染症および寄生虫症（続き）				
肺炎	Overall	-	1(0.8)	-
	Mild	-	1(0.8)	-
	Moderate	-	-	-
	Severe	-	-	-
細菌性肺炎	Overall	1(0.7)	-	-
	Mild	-	-	-
	Moderate	1(0.7)	-	-
	Severe	-	-	-
腎盂腎炎	Overall	-	1(0.8)	-
	Mild	-	-	-
	Moderate	-	1(0.8)	-
	Severe	-	-	-
白癬感染	Overall	-	-	1(0.8)
	Mild	-	-	1(0.8)
	Moderate	-	-	-
	Severe	-	-	-
扁桃炎	Overall	-	1(0.8)	-
	Mild	-	1(0.8)	-
	Moderate	-	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]　Statistical Analysis Report (5.3.5.1-3) Table 4.1.1.5

表 2.7.4.7-付録-18　有害事象の程度別発現頻度（CCT-002 試験）（17/44）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=141)	 0.5 mg (N=133)	 1 mg (N=129)
感染症および寄生虫症（続き）				
上気道感染	Overall	1(0.7)	-	-
	Mild	1(0.7)	-	-
	Moderate	-	-	-
	Severe	-	-	-
傷害、中毒および処置合併症	Overall	15(10.6)	19(14.3)	27(20.9)
	Mild	9(6.4)	12(9.0)	21(16.3)
	Moderate	6(4.3)	7(5.3)	5(3.9)
	Severe	-	-	1(0.8)
転倒	Overall	8(5.7)	13(9.8)	17(13.2)
	Mild	8(5.7)	11(8.3)	15(11.6)
	Moderate	-	2(1.5)	2(1.6)
	Severe	-	-	-
挫傷	Overall	2(1.4)	8(6.0)	7(5.4)
	Mild	2(1.4)	8(6.0)	6(4.7)
	Moderate	-	-	1(0.8)
	Severe	-	-	-
肋骨骨折	Overall	3(2.1)	1(0.8)	3(2.3)
	Mild	2(1.4)	-	3(2.3)
	Moderate	1(0.7)	1(0.8)	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]　Statistical Analysis Report (5.3.5.1-3) Table 4.1.1.5

表 2.7.4.7-付録-18　有害事象の程度別発現頻度（CCT-002 試験）（18/44）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=141)	 0.5 mg (N=133)	 1 mg (N=129)
傷害、中毒および処置合併症（続き）				
脊椎圧迫骨折	Overall	1(0.7)	1(0.8)	2(1.6)
	Mild	-	-	2(1.6)
	Moderate	1(0.7)	1(0.8)	-
	Severe	-	-	-
創傷	Overall	1(0.7)	-	3(2.3)
	Mild	-	-	2(1.6)
	Moderate	1(0.7)	-	1(0.8)
	Severe	-	-	-
靭帯捻挫	Overall	1(0.7)	-	2(1.6)
	Mild	-	-	2(1.6)
	Moderate	1(0.7)	-	-
	Severe	-	-	-
擦過傷	Overall	-	1(0.8)	1(0.8)
	Mild	-	1(0.8)	1(0.8)
	Moderate	-	-	-
	Severe	-	-	-
足骨折	Overall	2(1.4)	-	-
	Mild	1(0.7)	-	-
	Moderate	1(0.7)	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]. Statistical Analysis Report (5.3.5.1-3) Table 4.1.1.5

表 2.7.4.7-付録-18　有害事象の程度別発現頻度（CCT-002 試験）（19/44）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=141)	 0.5 mg (N=133)	 1 mg (N=129)
傷害、中毒および処置合併症（続き）				
裂傷	Overall	1(0.7)	-	1(0.8)
	Mild	1(0.7)	-	1(0.8)
	Moderate	-	-	-
	Severe	-	-	-
橈骨骨折	Overall	1(0.7)	-	1(0.8)
	Mild	1(0.7)	-	-
	Moderate	-	-	1(0.8)
	Severe	-	-	-
皮膚擦過傷	Overall	1(0.7)	1(0.8)	-
	Mild	1(0.7)	1(0.8)	-
	Moderate	-	-	-
	Severe	-	-	-
出血性吻合部潰瘍	Overall	-	1(0.8)	-
	Mild	-	-	-
	Moderate	-	1(0.8)	-
	Severe	-	-	-
口腔熱傷	Overall	-	-	1(0.8)
	Mild	-	-	1(0.8)
	Moderate	-	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.1-3) Table 4.1.1.5

表 2.7.4.7-付録-18　有害事象の程度別発現頻度（CCT-002 試験）（20/44）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=141)	 0.5 mg (N=133)	 1 mg (N=129)
傷害、中毒および処置合併症（続き）				
上顎炎	Overall	-	1(0.8)	-
	Mild	-	-	-
	Moderate	-	1(0.8)	-
	Severe	-	-	-
眼瞼挫傷	Overall	-	1(0.8)	-
	Mild	-	1(0.8)	-
	Moderate	-	-	-
	Severe	-	-	-
眼瞼損傷	Overall	-	1(0.8)	-
	Mild	-	1(0.8)	-
	Moderate	-	-	-
	Severe	-	-	-
大腿骨頚部骨折	Overall	-	-	1(0.8)
	Mild	-	-	-
	Moderate	-	-	-
	Severe	-	-	1(0.8)
術後胃腸障害	Overall	-	1(0.8)	-
	Mild	-	-	-
	Moderate	-	1(0.8)	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]　Statistical Analysis Report (5.3.5.1-3) Table 4.1.1.5

表 2.7.4.7-付録-18　有害事象の程度別発現頻度（CCT-002 試験）（21/44）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=141)	 0.5 mg (N=133)	 1 mg (N=129)
傷害、中毒および処置合併症（続き）				
熱中症	Overall	-	-	1(0.8)
	Mild	-	-	1(0.8)
	Moderate	-	-	-
	Severe	-	-	-
熱射病	Overall	-	1(0.8)	-
	Mild	-	1(0.8)	-
	Moderate	-	-	-
	Severe	-	-	-
口唇損傷	Overall	-	-	1(0.8)
	Mild	-	-	-
	Moderate	-	-	1(0.8)
	Severe	-	-	-
膝蓋骨骨折	Overall	1(0.7)	-	-
	Mild	-	-	-
	Moderate	1(0.7)	-	-
	Severe	-	-	-
交通事故	Overall	-	-	1(0.8)
	Mild	-	-	-
	Moderate	-	-	1(0.8)
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.1-3) Table 4.1.1.5

表 2.7.4.7-付録-18　有害事象の程度別発現頻度（CCT-002 試験）（22/44）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=141)	 0.5 mg (N=133)	 1 mg (N=129)
傷害、中毒および処置合併症（続き）				
熱傷	Overall	1(0.7)	-	-
	Mild	1(0.7)	-	-
	Moderate	-	-	-
	Severe	-	-	-
歯牙破折	Overall	-	-	1(0.8)
	Mild	-	-	-
	Moderate	-	-	1(0.8)
	Severe	-	-	-
歯牙損傷	Overall	-	-	1(0.8)
	Mild	-	-	1(0.8)
	Moderate	-	-	-
	Severe	-	-	-
上肢骨折	Overall	-	-	1(0.8)
	Mild	-	-	-
	Moderate	-	-	1(0.8)
	Severe	-	-	-
臨床検査	Overall	5(3.5)	9(6.8)	5(3.9)
	Mild	5(3.5)	9(6.8)	5(3.9)
	Moderate	-	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.1-3) Table 4.1.1.5

表 2.7.4.7-付録-18　有害事象の程度別発現頻度（CCT-002 試験）（23/44）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=141)	 0.5 mg (N=133)	 1 mg (N=129)
臨床検査（続き）				
体重減少	Overall	1(0.7)	1(0.8)	2(1.6)
	Mild	1(0.7)	1(0.8)	2(1.6)
	Moderate	-	-	-
	Severe	-	-	-
血中クレアチンホスホキナーゼ増加	Overall	1(0.7)	1(0.8)	1(0.8)
	Mild	1(0.7)	1(0.8)	1(0.8)
	Moderate	-	-	-
	Severe	-	-	-
尿中血陽性	Overall	-	2(1.5)	1(0.8)
	Mild	-	2(1.5)	1(0.8)
	Moderate	-	-	-
	Severe	-	-	-
γ－グルタミルトランスフェラーゼ増加	Overall	-	2(1.5)	-
	Mild	-	2(1.5)	-
	Moderate	-	-	-
	Severe	-	-	-
尿中蛋白陽性	Overall	1(0.7)	-	1(0.8)
	Mild	1(0.7)	-	1(0.8)
	Moderate	-	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.1-3) Table 4.1.1.5

表 2.7.4.7-付録-18　有害事象の程度別発現頻度（CCT-002 試験）（24/44）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=141)	 0.5 mg (N=133)	 1 mg (N=129)
臨床検査（続き）				
血中アルカリホスファターゼ増加	Overall	-	1(0.8)	-
	Mild	-	1(0.8)	-
	Moderate	-	-	-
	Severe	-	-	-
血中クレアチン増加	Overall	-	1(0.8)	-
	Mild	-	1(0.8)	-
	Moderate	-	-	-
	Severe	-	-	-
血圧低下	Overall	-	1(0.8)	-
	Mild	-	1(0.8)	-
	Moderate	-	-	-
	Severe	-	-	-
血圧上昇	Overall	1(0.7)	-	-
	Mild	1(0.7)	-	-
	Moderate	-	-	-
	Severe	-	-	-
尿中ブドウ糖陽性	Overall	1(0.7)	-	-
	Mild	1(0.7)	-	-
	Moderate	-	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.1-3) Table 4.1.1.5

表 2.7.4.7-付録-18　有害事象の程度別発現頻度（CCT-002 試験）（25/44）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=141)	 0.5 mg (N=133)	 1 mg (N=129)
臨床検査（続き）				
血小板数減少	Overall	-	-	1(0.8)
	Mild	-	-	1(0.8)
	Moderate	-	-	-
	Severe	-	-	-
尿中ケトン体陽性	Overall	1(0.7)	-	-
	Mild	1(0.7)	-	-
	Moderate	-	-	-
	Severe	-	-	-
白血球数減少	Overall	-	1(0.8)	-
	Mild	-	1(0.8)	-
	Moderate	-	-	-
	Severe	-	-	-
代謝および栄養障害	Overall	2(1.4)	2(1.5)	3(2.3)
	Mild	2(1.4)	1(0.8)	1(0.8)
	Moderate	-	1(0.8)	2(1.6)
	Severe	-	-	-
脱水	Overall	-	-	3(2.3)
	Mild	-	-	1(0.8)
	Moderate	-	-	2(1.6)
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.1-3) Table 4.1.1.5

表 2.7.4.7-付録-18　有害事象の程度別発現頻度（CCT-002 試験）（26/44）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=141)	 0.5 mg (N=133)	 1 mg (N=129)
代謝および栄養障害（続き）				
食欲減退	Overall	-	1(0.8)	-
	Mild	-	1(0.8)	-
	Moderate	-	-	-
	Severe	-	-	-
糖尿病	Overall	-	1(0.8)	-
	Mild	-	-	-
	Moderate	-	1(0.8)	-
	Severe	-	-	-
高カリウム血症	Overall	1(0.7)	-	-
	Mild	1(0.7)	-	-
	Moderate	-	-	-
	Severe	-	-	-
高尿酸血症	Overall	1(0.7)	-	-
	Mild	1(0.7)	-	-
	Moderate	-	-	-
	Severe	-	-	-
筋骨格系および結合組織障害	Overall	3(2.1)	13(9.8)	8(6.2)
	Mild	2(1.4)	10(7.5)	7(5.4)
	Moderate	1(0.7)	3(2.3)	1(0.8)
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.1-3) Table 4.1.1.5

表 2.7.4.7-付録-18　有害事象の程度別発現頻度（CCT-002 試験）（27/44）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=141)	 0.5 mg (N=133)	 1 mg (N=129)
筋骨格系および結合組織障害（続き）				
背部痛	Overall	-	2(1.5)	2(1.6)
	Mild	-	2(1.5)	2(1.6)
	Moderate	-	-	-
	Severe	-	-	-
関節痛	Overall	1(0.7)	1(0.8)	1(0.8)
	Mild	-	1(0.8)	1(0.8)
	Moderate	1(0.7)	-	-
	Severe	-	-	-
変形性関節症	Overall	2(1.4)	-	1(0.8)
	Mild	1(0.7)	-	-
	Moderate	1(0.7)	-	1(0.8)
	Severe	-	-	-
関節炎	Overall	-	2(1.5)	-
	Mild	-	1(0.8)	-
	Moderate	-	1(0.8)	-
	Severe	-	-	-
滑液包炎	Overall	-	2(1.5)	-
	Mild	-	2(1.5)	-
	Moderate	-	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.1-3) Table 4.1.1.5

表 2.7.4.7-付録-18　有害事象の程度別発現頻度（CCT-002 試験）（28/44）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=141)	 0.5 mg (N=133)	 1 mg (N=129)
筋骨格系および結合組織障害（続き）				
筋骨格硬直	Overall	-	1(0.8)	1(0.8)
	Mild	-	1(0.8)	1(0.8)
	Moderate	-	-	-
	Severe	-	-	-
骨粗鬆症	Overall	-	-	2(1.6)
	Mild	-	-	2(1.6)
	Moderate	-	-	-
	Severe	-	-	-
四肢痛	Overall	-	1(0.8)	1(0.8)
	Mild	-	1(0.8)	1(0.8)
	Moderate	-	-	-
	Severe	-	-	-
体幹前屈症	Overall	-	1(0.8)	-
	Mild	-	-	-
	Moderate	-	1(0.8)	-
	Severe	-	-	-
筋骨格痛	Overall	-	-	1(0.8)
	Mild	-	-	1(0.8)
	Moderate	-	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.1-3) Table 4.1.1.5

表 2.7.4.7-付録-18　有害事象の程度別発現頻度（CCT-002 試験）（29/44）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=141)	 0.5 mg (N=133)	 1 mg (N=129)
筋骨格系および結合組織障害（続き）				
関節周囲炎	Overall	-	1(0.8)	-
	Mild	-	1(0.8)	-
	Moderate	-	-	-
	Severe	-	-	-
肩回旋筋腱板症候群	Overall	-	1(0.8)	-
	Mild	-	-	-
	Moderate	-	1(0.8)	-
	Severe	-	-	-
脊柱管狭窄症	Overall	-	1(0.8)	-
	Mild	-	1(0.8)	-
	Moderate	-	-	-
	Severe	-	-	-
脊椎すべり症	Overall	1(0.7)	-	-
	Mild	1(0.7)	-	-
	Moderate	-	-	-
	Severe	-	-	-
顎関節症候群	Overall	-	-	1(0.8)
	Mild	-	-	1(0.8)
	Moderate	-	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.1-3) Table 4.1.1.5

表 2.7.4.7-付録-18　有害事象の程度別発現頻度（CCT-002 試験）（30/44）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=141)	 0.5 mg (N=133)	 1 mg (N=129)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	Overall	-	3(2.3)	-
	Mild	-	-	-
	Moderate	-	2(1.5)	-
	Severe	-	1(0.8)	-
乳癌	Overall	-	1(0.8)	-
	Mild	-	-	-
	Moderate	-	1(0.8)	-
	Severe	-	-	-
リンパ節転移	Overall	-	1(0.8)	-
	Mild	-	-	-
	Moderate	-	-	-
	Severe	-	1(0.8)	-
遠隔転移を伴う食道癌	Overall	-	1(0.8)	-
	Mild	-	-	-
	Moderate	-	-	-
	Severe	-	1(0.8)	-
甲状腺癌	Overall	-	1(0.8)	-
	Mild	-	-	-
	Moderate	-	1(0.8)	-
	Severe	-	-	-
神経系障害	Overall	18(12.8)	21(15.8)	37(28.7)
	Mild	11(7.8)	15(11.3)	23(17.8)
	Moderate	4(2.8)	6(4.5)	13(10.1)
	Severe	3(2.1)	-	1(0.8)

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.1-3) Table 4.1.1.5

表 2.7.4.7-付録-18　有害事象の程度別発現頻度（CCT-002 試験）（31/44）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=141)	 0.5 mg (N=133)	 1 mg (N=129)
神経系障害（続き）				
ジスキネジア	Overall	10(7.1)	11(8.3)	21(16.3)
	Mild	7(5.0)	9(6.8)	11(8.5)
	Moderate	2(1.4)	2(1.5)	10(7.8)
	Severe	1(0.7)	-	-
浮動性めまい	Overall	1(0.7)	4(3.0)	3(2.3)
	Mild	1(0.7)	4(3.0)	3(2.3)
	Moderate	-	-	-
	Severe	-	-	-
頭痛	Overall	-	3(2.3)	4(3.1)
	Mild	-	2(1.5)	3(2.3)
	Moderate	-	1(0.8)	1(0.8)
	Severe	-	-	-
傾眠	Overall	1(0.7)	1(0.8)	4(3.1)
	Mild	1(0.7)	1(0.8)	3(2.3)
	Moderate	-	-	1(0.8)
	Severe	-	-	-
パーキンソニズム	Overall	3(2.1)	-	1(0.8)
	Mild	1(0.7)	-	-
	Moderate	1(0.7)	-	1(0.8)
	Severe	1(0.7)	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.1-3) Table 4.1.1.5

表 2.7.4.7-付録-18　有害事象の程度別発現頻度（CCT-002 試験）（32/44）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=141)	 0.5 mg (N=133)	 1 mg (N=129)
神経系障害（続き）				
味覚異常	Overall	-	-	3(2.3)
	Mild	-	-	3(2.3)
	Moderate	-	-	-
	Severe	-	-	-
橈骨神経麻痺	Overall	1(0.7)	2(1.5)	-
	Mild	1(0.7)	-	-
	Moderate	-	2(1.5)	-
	Severe	-	-	-
下肢静止不能症候群	Overall	-	1(0.8)	1(0.8)
	Mild	-	1(0.8)	1(0.8)
	Moderate	-	-	-
	Severe	-	-	-
頚腕症候群	Overall	-	-	1(0.8)
	Mild	-	-	1(0.8)
	Moderate	-	-	-
	Severe	-	-	-
認知障害	Overall	1(0.7)	-	-
	Mild	-	-	-
	Moderate	1(0.7)	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.1-3) Table 4.1.1.5

表 2.7.4.7-付録-18　有害事象の程度別発現頻度（CCT-002 試験）（33/44）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=141)	 0.5 mg (N=133)	 1 mg (N=129)
神経系障害（続き）				
体位性めまい	Overall	-	-	1(0.8)
	Mild	-	-	1(0.8)
	Moderate	-	-	-
	Severe	-	-	-
頭部下垂症候群	Overall	-	1(0.8)	-
	Mild	-	-	-
	Moderate	-	1(0.8)	-
	Severe	-	-	-
異常感覚	Overall	1(0.7)	-	-
	Mild	1(0.7)	-	-
	Moderate	-	-	-
	Severe	-	-	-
すくみ現象	Overall	-	-	1(0.8)
	Mild	-	-	1(0.8)
	Moderate	-	-	-
	Severe	-	-	-
頭蓋内出血	Overall	1(0.7)	-	-
	Mild	-	-	-
	Moderate	-	-	-
	Severe	1(0.7)	-	-

有害事象名：MedDRA/J ver[redacted]. Statistical Analysis Report (5.3.5.1-3) Table 4.1.1.5

表 2.7.4.7-付録-18　有害事象の程度別発現頻度（CCT-002 試験）（34/44）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=141)	 0.5 mg (N=133)	 1 mg (N=129)
神経系障害（続き）				
感覚鈍麻	Overall	-	-	1(0.8)
	Mild	-	-	1(0.8)
	Moderate	-	-	-
	Severe	-	-	-
低酸素性虚血性脳症	Overall	-	-	1(0.8)
	Mild	-	-	-
	Moderate	-	-	-
	Severe	-	-	1(0.8)
突発的睡眠	Overall	1(0.7)	-	-
	Mild	1(0.7)	-	-
	Moderate	-	-	-
	Severe	-	-	-
失神	Overall	-	-	1(0.8)
	Mild	-	-	1(0.8)
	Moderate	-	-	-
	Severe	-	-	-
緊張性頭痛	Overall	-	-	1(0.8)
	Mild	-	-	1(0.8)
	Moderate	-	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.1-3) Table 4.1.1.5

表 2.7.4.7-付録-18　有害事象の程度別発現頻度（CCT-002 試験）（35/44）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=141)	 0.5 mg (N=133)	 1 mg (N=129)
精神障害	Overall	5(3.5)	11(8.3)	10(7.8)
	Mild	5(3.5)	8(6.0)	7(5.4)
	Moderate	-	2(1.5)	3(2.3)
	Severe	-	1(0.8)	-
幻覚	Overall	1(0.7)	5(3.8)	5(3.9)
	Mild	1(0.7)	3(2.3)	2(1.6)
	Moderate	-	1(0.8)	3(2.3)
	Severe	-	1(0.8)	-
不眠症	Overall	3(2.1)	1(0.8)	2(1.6)
	Mild	3(2.1)	1(0.8)	2(1.6)
	Moderate	-	-	-
	Severe	-	-	-
幻視	Overall	-	2(1.5)	-
	Mild	-	1(0.8)	-
	Moderate	-	1(0.8)	-
	Severe	-	-	-
睡眠発作	Overall	-	-	2(1.6)
	Mild	-	-	2(1.6)
	Moderate	-	-	-
	Severe	-	-	-
異常な夢	Overall	-	1(0.8)	-
	Mild	-	1(0.8)	-
	Moderate	-	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.1-3) Table 4.1.1.5

表 2.7.4.7-付録-18　有害事象の程度別発現頻度（CCT-002 試験）（36/44）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=141)	 0.5 mg (N=133)	 1 mg (N=129)
精神障害（続き）				
攻撃性	Overall	1(0.7)	-	-
	Mild	1(0.7)	-	-
	Moderate	-	-	-
	Severe	-	-	-
譫妄	Overall	-	-	1(0.8)
	Mild	-	-	1(0.8)
	Moderate	-	-	-
	Severe	-	-	-
幻聴	Overall	-	-	1(0.8)
	Mild	-	-	1(0.8)
	Moderate	-	-	-
	Severe	-	-	-
性欲過剰	Overall	-	1(0.8)	-
	Mild	-	1(0.8)	-
	Moderate	-	-	-
	Severe	-	-	-
人格変化	Overall	-	1(0.8)	-
	Mild	-	1(0.8)	-
	Moderate	-	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.1-3) Table 4.1.1.5

表 2.7.4.7-付録-18　有害事象の程度別発現頻度（CCT-002 試験）（37/44）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=141)	 0.5 mg (N=133)	 1 mg (N=129)
精神障害（続き）				
睡眠障害	Overall	-	-	1(0.8)
	Mild	-	-	1(0.8)
	Moderate	-	-	-
	Severe	-	-	-
ねごと	Overall	1(0.7)	-	-
	Mild	1(0.7)	-	-
	Moderate	-	-	-
	Severe	-	-	-
腎および尿路障害	Overall	2(1.4)	3(2.3)	1(0.8)
	Mild	2(1.4)	2(1.5)	-
	Moderate	-	1(0.8)	1(0.8)
	Severe	-	-	-
緊張性膀胱	Overall	-	2(1.5)	-
	Mild	-	1(0.8)	-
	Moderate	-	1(0.8)	-
	Severe	-	-	-
腎機能障害	Overall	1(0.7)	1(0.8)	-
	Mild	1(0.7)	1(0.8)	-
	Moderate	-	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.1-3) Table 4.1.1.5

表 2.7.4.7-付録-18　有害事象の程度別発現頻度（CCT-002 試験）（38/44）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=141)	 0.5 mg (N=133)	 1 mg (N=129)
腎および尿路障害（続き）				
排尿異常	Overall	-	-	1(0.8)
	Mild	-	-	-
	Moderate	-	-	1(0.8)
	Severe	-	-	-
頻尿	Overall	1(0.7)	-	-
	Mild	1(0.7)	-	-
	Moderate	-	-	-
	Severe	-	-	-
生殖系および乳房障害	Overall	-	1(0.8)	-
	Mild	-	1(0.8)	-
	Moderate	-	-	-
	Severe	-	-	-
萎縮性外陰腟炎	Overall	-	1(0.8)	-
	Mild	-	1(0.8)	-
	Moderate	-	-	-
	Severe	-	-	-
呼吸器、胸郭および縦隔障害	Overall	4(2.8)	6(4.5)	3(2.3)
	Mild	4(2.8)	5(3.8)	2(1.6)
	Moderate	-	1(0.8)	1(0.8)
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.1-3) Table 4.1.1.5

表 2.7.4.7-付録-18　有害事象の程度別発現頻度（CCT-002 試験）（39/44）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=141)	 0.5 mg (N=133)	 1 mg (N=129)
呼吸器、胸郭および縦隔障害（続き）				
上気道の炎症	Overall	3(2.1)	1(0.8)	1(0.8)
	Mild	3(2.1)	1(0.8)	1(0.8)
	Moderate	-	-	-
	Severe	-	-	-
口腔咽頭痛	Overall	-	1(0.8)	1(0.8)
	Mild	-	1(0.8)	1(0.8)
	Moderate	-	-	-
	Severe	-	-	-
アレルギー性鼻炎	Overall	-	2(1.5)	-
	Mild	-	2(1.5)	-
	Moderate	-	-	-
	Severe	-	-	-
慢性気管支炎	Overall	-	1(0.8)	-
	Mild	-	1(0.8)	-
	Moderate	-	-	-
	Severe	-	-	-
咳嗽	Overall	1(0.7)	-	-
	Mild	1(0.7)	-	-
	Moderate	-	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.1-3) Table 4.1.1.5

表 2.7.4.7-付録-18　有害事象の程度別発現頻度（CCT-002 試験）（40/44）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=141)	 0.5 mg (N=133)	 1 mg (N=129)
呼吸器、胸郭および縦隔障害（続き）				
鼻出血	Overall	-	-	1(0.8)
	Mild	-	-	-
	Moderate	-	-	1(0.8)
	Severe	-	-	-
間質性肺疾患	Overall	-	1(0.8)	-
	Mild	-	-	-
	Moderate	-	1(0.8)	-
	Severe	-	-	-
皮膚および皮下組織障害	Overall	7(5.0)	8(6.0)	11(8.5)
	Mild	5(3.5)	8(6.0)	10(7.8)
	Moderate	2(1.4)	-	1(0.8)
	Severe	-	-	-
湿疹	Overall	1(0.7)	3(2.3)	2(1.6)
	Mild	-	3(2.3)	2(1.6)
	Moderate	1(0.7)	-	-
	Severe	-	-	-
皮下出血	Overall	1(0.7)	-	2(1.6)
	Mild	1(0.7)	-	2(1.6)
	Moderate	-	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.1-3) Table 4.1.1.5

表 2.7.4.7-付録-18　有害事象の程度別発現頻度（CCT-002 試験）（41/44）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=141)	 0.5 mg (N=133)	 1 mg (N=129)
皮膚および皮下組織障害（続き）				
汗疹	Overall	-	2(1.5)	1(0.8)
	Mild	-	2(1.5)	1(0.8)
	Moderate	-	-	-
	Severe	-	-	-
褥瘡性潰瘍	Overall	-	1(0.8)	1(0.8)
	Mild	-	1(0.8)	1(0.8)
	Moderate	-	-	-
	Severe	-	-	-
多汗症	Overall	-	-	2(1.6)
	Mild	-	-	2(1.6)
	Moderate	-	-	-
	Severe	-	-	-
皮膚嚢腫	Overall	1(0.7)	-	-
	Mild	1(0.7)	-	-
	Moderate	-	-	-
	Severe	-	-	-
皮膚炎	Overall	-	1(0.8)	-
	Mild	-	1(0.8)	-
	Moderate	-	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.1-3) Table 4.1.1.5

表 2.7.4.7-付録-18　有害事象の程度別発現頻度（CCT-002 試験）（42/44）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=141)	 0.5 mg (N=133)	 1 mg (N=129)
皮膚および皮下組織障害（続き）				
アレルギー性皮膚炎	Overall	1(0.7)	-	-
	Mild	1(0.7)	-	-
	Moderate	-	-	-
	Severe	-	-	-
接触性皮膚炎	Overall	1(0.7)	-	-
	Mild	1(0.7)	-	-
	Moderate	-	-	-
	Severe	-	-	-
薬疹	Overall	1(0.7)	-	-
	Mild	1(0.7)	-	-
	Moderate	-	-	-
	Severe	-	-	-
発疹	Overall	-	-	1(0.8)
	Mild	-	-	1(0.8)
	Moderate	-	-	-
	Severe	-	-	-
脂漏性皮膚炎	Overall	-	-	1(0.8)
	Mild	-	-	-
	Moderate	-	-	1(0.8)
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.1-3) Table 4.1.1.5

表 2.7.4.7-付録-18　有害事象の程度別発現頻度（CCT-002 試験）（43/44）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=141)	 0.5 mg (N=133)	 1 mg (N=129)
皮膚および皮下組織障害（続き）				
皮膚腫瘤	Overall	-	-	1(0.8)
	Mild	-	-	1(0.8)
	Moderate	-	-	-
	Severe	-	-	-
皮膚潰瘍	Overall	1(0.7)	-	-
	Mild	-	-	-
	Moderate	1(0.7)	-	-
	Severe	-	-	-
蕁麻疹	Overall	-	1(0.8)	-
	Mild	-	1(0.8)	-
	Moderate	-	-	-
	Severe	-	-	-
血管障害	Overall	-	4(3.0)	8(6.2)
	Mild	-	2(1.5)	3(2.3)
	Moderate	-	2(1.5)	5(3.9)
	Severe	-	-	-
起立性低血圧	Overall	-	2(1.5)	3(2.3)
	Mild	-	-	1(0.8)
	Moderate	-	2(1.5)	2(1.6)
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.1-3) Table 4.1.1.5

表 2.7.4.7-付録-18　有害事象の程度別発現頻度（CCT-002 試験）（44/44）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=141)	 0.5 mg (N=133)	 1 mg (N=129)
血管障害（続き）				
高血圧	Overall	-	1(0.8)	1(0.8)
	Mild	-	1(0.8)	1(0.8)
	Moderate	-	-	-
	Severe	-	-	-
低血圧	Overall	-	-	2(1.6)
	Mild	-	-	-
	Moderate	-	-	2(1.6)
	Severe	-	-	-
血圧変動	Overall	-	-	1(0.8)
	Mild	-	-	-
	Moderate	-	-	1(0.8)
	Severe	-	-	-
内出血	Overall	-	-	1(0.8)
	Mild	-	-	1(0.8)
	Moderate	-	-	-
	Severe	-	-	-
末梢冷感	Overall	-	1(0.8)	-
	Mild	-	1(0.8)	-
	Moderate	-	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.1-3) Table 4.1.1.5

表 2.7.4.7-付録-19　有害事象の程度別発現頻度（133 試験）（1/97）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=159)	 0.5 mg (N=164)	 1 mg (N=149)
Subjects with Any TEAEs	Overall	139(87.4)	149(90.9)	141(94.6)
	Mild	48(30.2)	40(24.4)	51(34.2)
	Moderate	70(44.0)	84(51.2)	65(43.6)
	Severe	21(13.2)	25(15.2)	25(16.8)
血液およびリンパ系障害	Overall	3(1.9)	3(1.8)	4(2.7)
	Mild	-	2(1.2)	2(1.3)
	Moderate	3(1.9)	1(0.6)	2(1.3)
	Severe	-	-	-
貧血	Overall	2(1.3)	1(0.6)	3(2.0)
	Mild	-	-	2(1.3)
	Moderate	2(1.3)	1(0.6)	1(0.7)
	Severe	-	-	-
鉄欠乏性貧血	Overall	1(0.6)	1(0.6)	-
	Mild	-	1(0.6)	-
	Moderate	1(0.6)	-	-
	Severe	-	-	-
内出血発生の増加傾向	Overall	-	1(0.6)	-
	Mild	-	1(0.6)	-
	Moderate	-	-	-
	Severe	-	-	-
悪性貧血	Overall	-	-	1(0.7)
	Mild	-	-	-
	Moderate	-	-	1(0.7)
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.1.1.5

表 2.7.4.7-付録-19　有害事象の程度別発現頻度（133 試験）（2/97）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=159)	 0.5 mg (N=164)	 1 mg (N=149)
心臓障害	Overall	5(3.1)	10(6.1)	4(2.7)
	Mild	2(1.3)	3(1.8)	2(1.3)
	Moderate	3(1.9)	4(2.4)	1(0.7)
	Severe	-	3(1.8)	1(0.7)
第一度房室ブロック	Overall	2(1.3)	-	1(0.7)
	Mild	1(0.6)	-	1(0.7)
	Moderate	1(0.6)	-	-
	Severe	-	-	-
頻脈	Overall	1(0.6)	2(1.2)	-
	Mild	-	2(1.2)	-
	Moderate	1(0.6)	-	-
	Severe	-	-	-
うっ血性心不全	Overall	-	1(0.6)	1(0.7)
	Mild	-	-	-
	Moderate	-	-	1(0.7)
	Severe	-	1(0.6)	-
心室性期外収縮	Overall	1(0.6)	1(0.6)	-
	Mild	-	1(0.6)	-
	Moderate	1(0.6)	-	-
	Severe	-	-	-
不安定狭心症	Overall	-	1(0.6)	-
	Mild	-	-	-
	Moderate	-	-	-
	Severe	-	1(0.6)	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.1.1.5

表 2.7.4.7-付録-19　有害事象の程度別発現頻度（133 試験）（3/97）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=159)	 0.5 mg (N=164)	 1 mg (N=149)
心臓障害（続き）				
不整脈	Overall	-	1(0.6)	-
	Mild	-	-	-
	Moderate	-	1(0.6)	-
	Severe	-	-	-
心房頻脈	Overall	-	1(0.6)	-
	Mild	-	-	-
	Moderate	-	1(0.6)	-
	Severe	-	-	-
徐脈	Overall	-	-	1(0.7)
	Mild	-	-	-
	Moderate	-	-	1(0.7)
	Severe	-	-	-
右脚ブロック	Overall	1(0.6)	-	-
	Mild	-	-	-
	Moderate	1(0.6)	-	-
	Severe	-	-	-
心停止	Overall	-	1(0.6)	-
	Mild	-	-	-
	Moderate	-	-	-
	Severe	-	1(0.6)	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.1.1.5

表 2.7.4.7-付録-19　有害事象の程度別発現頻度（133 試験）（4/97）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=159)	 0.5 mg (N=164)	 1 mg (N=149)
心臓障害（続き）				
冠動脈疾患	Overall	1(0.6)	-	-
	Mild	1(0.6)	-	-
	Moderate	-	-	-
	Severe	-	-	-
冠動脈閉塞	Overall	-	1(0.6)	-
	Mild	-	-	-
	Moderate	-	-	-
	Severe	-	1(0.6)	-
僧帽弁閉鎖不全症	Overall	-	1(0.6)	-
	Mild	-	1(0.6)	-
	Moderate	-	-	-
	Severe	-	-	-
動悸	Overall	-	-	1(0.7)
	Mild	-	-	1(0.7)
	Moderate	-	-	-
	Severe	-	-	-
洞性徐脈	Overall	1(0.6)	-	-
	Mild	1(0.6)	-	-
	Moderate	-	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.1.1.5

表 2.7.4.7-付録-19　有害事象の程度別発現頻度（133 試験）（5/97）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=159)	 0.5 mg (N=164)	 1 mg (N=149)
心臓障害（続き）				
洞結節機能不全	Overall	-	-	1(0.7)
	Mild	-	-	-
	Moderate	-	-	-
	Severe	-	-	1(0.7)
洞性頻脈	Overall	1(0.6)	-	-
	Mild	-	-	-
	Moderate	1(0.6)	-	-
	Severe	-	-	-
三尖弁閉鎖不全症	Overall	-	1(0.6)	-
	Mild	-	-	-
	Moderate	-	1(0.6)	-
	Severe	-	-	-
心室壁運動低下	Overall	-	1(0.6)	-
	Mild	-	1(0.6)	-
	Moderate	-	-	-
	Severe	-	-	-
心室性頻脈	Overall	-	1(0.6)	-
	Mild	-	-	-
	Moderate	-	1(0.6)	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.1.1.5

表 2.7.4.7-付録-19　有害事象の程度別発現頻度（133 試験）（6/97）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=159)	 0.5 mg (N=164)	 1 mg (N=149)
先天性、家族性および遺伝性障害	Overall	1(0.6)	-	-
	Mild	1(0.6)	-	-
	Moderate	-	-	-
	Severe	-	-	-
サラセミア	Overall	1(0.6)	-	-
	Mild	1(0.6)	-	-
	Moderate	-	-	-
	Severe	-	-	-
耳および迷路障害	Overall	3(1.9)	6(3.7)	1(0.7)
	Mild	2(1.3)	3(1.8)	1(0.7)
	Moderate	1(0.6)	2(1.2)	-
	Severe	-	1(0.6)	-
耳鳴	Overall	1(0.6)	1(0.6)	1(0.7)
	Mild	1(0.6)	1(0.6)	1(0.7)
	Moderate	-	-	-
	Severe	-	-	-
耳不快感	Overall	1(0.6)	1(0.6)	-
	Mild	1(0.6)	-	-
	Moderate	-	1(0.6)	-
	Severe	-	-	-
聴力低下	Overall	1(0.6)	1(0.6)	-
	Mild	-	-	-
	Moderate	1(0.6)	-	-
	Severe	-	1(0.6)	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.1.1.5

表 2.7.4.7-付録-19　有害事象の程度別発現頻度（133 試験）（7/97）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=159)	 0.5 mg (N=164)	 1 mg (N=149)
耳および迷路障害（続き）				
耳の障害	Overall	-	1(0.6)	-
	Mild	-	1(0.6)	-
	Moderate	-	-	-
	Severe	-	-	-
耳痛	Overall	-	1(0.6)	-
	Mild	-	1(0.6)	-
	Moderate	-	-	-
	Severe	-	-	-
耳漏	Overall	-	1(0.6)	-
	Mild	-	-	-
	Moderate	-	1(0.6)	-
	Severe	-	-	-
鼓膜穿孔	Overall	-	1(0.6)	-
	Mild	-	1(0.6)	-
	Moderate	-	-	-
	Severe	-	-	-
内分泌障害	Overall	-	2(1.2)	1(0.7)
	Mild	-	1(0.6)	-
	Moderate	-	1(0.6)	1(0.7)
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.1.1.5

表 2.7.4.7-付録-19　有害事象の程度別発現頻度（133 試験）（8/97）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=159)	 0.5 mg (N=164)	 1 mg (N=149)
内分泌障害（続き）				
甲状腺腫	Overall	-	1(0.6)	1(0.7)
	Mild	-	1(0.6)	-
	Moderate	-	-	1(0.7)
	Severe	-	-	-
甲状腺機能亢進症	Overall	-	1(0.6)	-
	Mild	-	-	-
	Moderate	-	1(0.6)	-
	Severe	-	-	-
眼障害	Overall	7(4.4)	3(1.8)	12(8.1)
	Mild	3(1.9)	1(0.6)	8(5.4)
	Moderate	4(2.5)	2(1.2)	3(2.0)
	Severe	-	-	1(0.7)
眼乾燥	Overall	2(1.3)	-	1(0.7)
	Mild	1(0.6)	-	1(0.7)
	Moderate	1(0.6)	-	-
	Severe	-	-	-
霧視	Overall	1(0.6)	-	2(1.3)
	Mild	1(0.6)	-	1(0.7)
	Moderate	-	-	-
	Severe	-	-	1(0.7)

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.1.1.5

表 2.7.4.7-付録-19　有害事象の程度別発現頻度（133 試験）（9/97）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=159)	 0.5 mg (N=164)	 1 mg (N=149)
眼障害（続き）				
眼充血	Overall	1(0.6)	-	1(0.7)
	Mild	1(0.6)	-	1(0.7)
	Moderate	-	-	-
	Severe	-	-	-
羞明	Overall	1(0.6)	-	1(0.7)
	Mild	-	-	-
	Moderate	1(0.6)	-	1(0.7)
	Severe	-	-	-
視力障害	Overall	-	-	2(1.3)
	Mild	-	-	-
	Moderate	-	-	2(1.3)
	Severe	-	-	-
アレルギー性眼瞼炎	Overall	-	1(0.6)	-
	Mild	-	-	-
	Moderate	-	1(0.6)	-
	Severe	-	-	-
結膜充血	Overall	1(0.6)	-	-
	Mild	-	-	-
	Moderate	1(0.6)	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]. Statistical Analysis Report (5.3.5.3-1) Table 2.1.1.5

表 2.7.4.7-付録-19　有害事象の程度別発現頻度（133 試験）（10/97）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=159)	 0.5 mg (N=164)	 1 mg (N=149)
眼障害（続き）				
アレルギー性結膜炎	Overall	-	1(0.6)	-
	Mild	-	-	-
	Moderate	-	1(0.6)	-
	Severe	-	-	-
複視	Overall	-	-	1(0.7)
	Mild	-	-	1(0.7)
	Moderate	-	-	-
	Severe	-	-	-
眼瞼紅斑	Overall	-	-	1(0.7)
	Mild	-	-	1(0.7)
	Moderate	-	-	-
	Severe	-	-	-
眼刺激	Overall	-	1(0.6)	-
	Mild	-	1(0.6)	-
	Moderate	-	-	-
	Severe	-	-	-
眼そう痒症	Overall	-	-	1(0.7)
	Mild	-	-	1(0.7)
	Moderate	-	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.1.1.5

表 2.7.4.7-付録-19　有害事象の程度別発現頻度（133 試験）（11/97）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=159)	 0.5 mg (N=164)	 1 mg (N=149)
眼障害（続き）				
緑内障	Overall	1(0.6)	-	-
	Mild	-	-	-
	Moderate	1(0.6)	-	-
	Severe	-	-	-
眼部不快感	Overall	-	-	1(0.7)
	Mild	-	-	1(0.7)
	Moderate	-	-	-
	Severe	-	-	-
視力低下	Overall	-	-	1(0.7)
	Mild	-	-	1(0.7)
	Moderate	-	-	-
	Severe	-	-	-
硝子体浮遊物	Overall	-	-	1(0.7)
	Mild	-	-	1(0.7)
	Moderate	-	-	-
	Severe	-	-	-
胃腸障害	Overall	47(29.6)	48(29.3)	44(29.5)
	Mild	26(16.4)	24(14.6)	22(14.8)
	Moderate	21(13.2)	17(10.4)	17(11.4)
	Severe	-	7(4.3)	5(3.4)

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.1.1.5

表 2.7.4.7-付録-19　有害事象の程度別発現頻度（133 試験）（12/97）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=159)	 0.5 mg (N=164)	 1 mg (N=149)
胃腸障害（続き）				
悪心	Overall	13(8.2)	16(9.8)	18(12.1)
	Mild	10(6.3)	12(7.3)	13(8.7)
	Moderate	3(1.9)	3(1.8)	5(3.4)
	Severe	-	1(0.6)	-
便秘	Overall	8(5.0)	6(3.7)	13(8.7)
	Mild	4(2.5)	3(1.8)	7(4.7)
	Moderate	4(2.5)	2(1.2)	6(4.0)
	Severe	-	1(0.6)	-
下痢	Overall	6(3.8)	10(6.1)	7(4.7)
	Mild	4(2.5)	5(3.0)	5(3.4)
	Moderate	2(1.3)	2(1.2)	2(1.3)
	Severe	-	3(1.8)	-
口内乾燥	Overall	5(3.1)	4(2.4)	9(6.0)
	Mild	2(1.3)	3(1.8)	7(4.7)
	Moderate	3(1.9)	1(0.6)	2(1.3)
	Severe	-	-	-
嘔吐	Overall	2(1.3)	6(3.7)	10(6.7)
	Mild	1(0.6)	4(2.4)	7(4.7)
	Moderate	1(0.6)	1(0.6)	3(2.0)
	Severe	-	1(0.6)	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.1.1.5

表 2.7.4.7-付録-19　有害事象の程度別発現頻度（133 試験）（13/97）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=159)	 0.5 mg (N=164)	 1 mg (N=149)
胃腸障害（続き）				
消化不良	Overall	3(1.9)	4(2.4)	2(1.3)
	Mild	3(1.9)	3(1.8)	-
	Moderate	-	1(0.6)	1(0.7)
	Severe	-	-	1(0.7)
上腹部痛	Overall	2(1.3)	4(2.4)	2(1.3)
	Mild	-	2(1.2)	-
	Moderate	2(1.3)	-	2(1.3)
	Severe	-	2(1.2)	-
腹痛	Overall	-	1(0.6)	6(4.0)
	Mild	-	1(0.6)	1(0.7)
	Moderate	-	-	3(2.0)
	Severe	-	-	2(1.3)
腹部不快感	Overall	2(1.3)	-	4(2.7)
	Mild	1(0.6)	-	3(2.0)
	Moderate	1(0.6)	-	1(0.7)
	Severe	-	-	-
歯痛	Overall	3(1.9)	2(1.2)	1(0.7)
	Mild	-	1(0.6)	1(0.7)
	Moderate	3(1.9)	1(0.6)	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.1.1.5

表 2.7.4.7-付録-19　有害事象の程度別発現頻度（133 試験）（14/97）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=159)	 0.5 mg (N=164)	 1 mg (N=149)
胃腸障害（続き）				
齲歯	Overall	2(1.3)	1(0.6)	1(0.7)
	Mild	-	-	-
	Moderate	2(1.3)	1(0.6)	1(0.7)
	Severe	-	-	-
胃食道逆流性疾患	Overall	1(0.6)	2(1.2)	1(0.7)
	Mild	1(0.6)	1(0.6)	1(0.7)
	Moderate	-	1(0.6)	-
	Severe	-	-	-
嚥下障害	Overall	-	1(0.6)	2(1.3)
	Mild	-	1(0.6)	2(1.3)
	Moderate	-	-	-
	Severe	-	-	-
鼠径ヘルニア	Overall	1(0.6)	2(1.2)	-
	Mild	-	-	-
	Moderate	1(0.6)	2(1.2)	-
	Severe	-	-	-
腹部膨満	Overall	1(0.6)	-	1(0.7)
	Mild	1(0.6)	-	1(0.7)
	Moderate	-	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.1.1.5

表 2.7.4.7-付録-19　有害事象の程度別発現頻度（133 試験）（15/97）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=159)	 0.5 mg (N=164)	 1 mg (N=149)
胃腸障害（続き）				
軟便	Overall	-	1(0.6)	1(0.7)
	Mild	-	1(0.6)	1(0.7)
	Moderate	-	-	-
	Severe	-	-	-
大腸ポリープ	Overall	-	2(1.2)	-
	Mild	-	2(1.2)	-
	Moderate	-	-	-
	Severe	-	-	-
流涎過多	Overall	1(0.6)	1(0.6)	-
	Mild	1(0.6)	-	-
	Moderate	-	1(0.6)	-
	Severe	-	-	-
歯の障害	Overall	1(0.6)	1(0.6)	-
	Mild	-	1(0.6)	-
	Moderate	1(0.6)	-	-
	Severe	-	-	-
腹部硬直	Overall	-	1(0.6)	-
	Mild	-	1(0.6)	-
	Moderate	-	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]　Statistical Analysis Report (5.3.5.3-1) Table 2.1.1.5

表 2.7.4.7-付録-19　有害事象の程度別発現頻度（133 試験）（16/97）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=159)	 0.5 mg (N=164)	 1 mg (N=149)
胃腸障害（続き）				
アフタ性潰瘍	Overall	1(0.6)	-	-
	Mild	1(0.6)	-	-
	Moderate	-	-	-
	Severe	-	-	-
呼気臭	Overall	-	-	1(0.7)
	Mild	-	-	1(0.7)
	Moderate	-	-	-
	Severe	-	-	-
大腸炎	Overall	1(0.6)	-	-
	Mild	-	-	-
	Moderate	1(0.6)	-	-
	Severe	-	-	-
潰瘍性大腸炎	Overall	1(0.6)	-	-
	Mild	1(0.6)	-	-
	Moderate	-	-	-
	Severe	-	-	-
クローン病	Overall	1(0.6)	-	-
	Mild	1(0.6)	-	-
	Moderate	-	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]. Statistical Analysis Report (5.3.5.3-1) Table 2.1.1.5

表 2.7.4.7-付録-19　有害事象の程度別発現頻度（133 試験）（17/97）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=159)	 0.5 mg (N=164)	 1 mg (N=149)
胃腸障害（続き）				
十二指腸潰瘍	Overall	-	1(0.6)	-
	Mild	-	-	-
	Moderate	-	-	-
	Severe	-	1(0.6)	-
おくび	Overall	1(0.6)	-	-
	Mild	1(0.6)	-	-
	Moderate	-	-	-
	Severe	-	-	-
胃粘膜紅斑	Overall	-	-	1(0.7)
	Mild	-	-	1(0.7)
	Moderate	-	-	-
	Severe	-	-	-
胃潰瘍	Overall	-	1(0.6)	-
	Mild	-	-	-
	Moderate	-	-	-
	Severe	-	1(0.6)	-
胃炎	Overall	-	1(0.6)	-
	Mild	-	-	-
	Moderate	-	1(0.6)	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]. Statistical Analysis Report (5.3.5.3-1) Table 2.1.1.5

表 2.7.4.7-付録-19　有害事象の程度別発現頻度（133 試験）（18/97）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=159)	 0.5 mg (N=164)	 1 mg (N=149)
胃腸障害（続き）				
歯肉障害	Overall	1(0.6)	-	-
	Mild	1(0.6)	-	-
	Moderate	-	-	-
	Severe	-	-	-
歯肉痛	Overall	1(0.6)	-	-
	Mild	1(0.6)	-	-
	Moderate	-	-	-
	Severe	-	-	-
裂孔ヘルニア	Overall	-	-	1(0.7)
	Mild	-	-	1(0.7)
	Moderate	-	-	-
	Severe	-	-	-
胃酸過多	Overall	-	1(0.6)	-
	Mild	-	1(0.6)	-
	Moderate	-	-	-
	Severe	-	-	-
口の感覚鈍麻	Overall	-	1(0.6)	-
	Mild	-	-	-
	Moderate	-	1(0.6)	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]　Statistical Analysis Report (5.3.5.3-1) Table 2.1.1.5

表 2.7.4.7-付録-19　有害事象の程度別発現頻度（133 試験）（19/97）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=159)	 0.5 mg (N=164)	 1 mg (N=149)
胃腸障害（続き）				
腸閉塞	Overall	-	-	1(0.7)
	Mild	-	-	-
	Moderate	-	-	-
	Severe	-	-	1(0.7)
過敏性腸症候群	Overall	1(0.6)	-	-
	Mild	-	-	-
	Moderate	1(0.6)	-	-
	Severe	-	-	-
弛緩歯	Overall	1(0.6)	-	-
	Mild	-	-	-
	Moderate	1(0.6)	-	-
	Severe	-	-	-
吸収不良	Overall	1(0.6)	-	-
	Mild	-	-	-
	Moderate	1(0.6)	-	-
	Severe	-	-	-
食道痙攣	Overall	-	1(0.6)	-
	Mild	-	-	-
	Moderate	-	1(0.6)	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.1.1.5

表 2.7.4.7-付録-19　有害事象の程度別発現頻度（133 試験）（20/97）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=159)	 0.5 mg (N=164)	 1 mg (N=149)
胃腸障害（続き）				
食道炎	Overall	-	1(0.6)	-
	Mild	-	-	-
	Moderate	-	1(0.6)	-
	Severe	-	-	-
口腔障害	Overall	1(0.6)	-	-
	Mild	1(0.6)	-	-
	Moderate	-	-	-
	Severe	-	-	-
レッチング	Overall	-	-	1(0.7)
	Mild	-	-	-
	Moderate	-	-	-
	Severe	-	-	1(0.7)
小腸閉塞	Overall	-	-	1(0.7)
	Mild	-	-	-
	Moderate	-	-	1(0.7)
	Severe	-	-	-
口内炎	Overall	1(0.6)	-	-
	Mild	1(0.6)	-	-
	Moderate	-	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.1.1.5

表 2.7.4.7-付録-19　有害事象の程度別発現頻度（133 試験）（21/97）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=159)	 0.5 mg (N=164)	 1 mg (N=149)
胃腸障害（続き）				
歯の脱落	Overall	1(0.6)	-	-
	Mild	1(0.6)	-	-
	Moderate	-	-	-
	Severe	-	-	-
上部消化管出血	Overall	-	1(0.6)	-
	Mild	-	-	-
	Moderate	-	-	-
	Severe	-	1(0.6)	-
一般・全身障害および投与部位の状態	Overall	39(24.5)	20(12.2)	27(18.1)
	Mild	20(12.6)	10(6.1)	16(10.7)
	Moderate	17(10.7)	10(6.1)	10(6.7)
	Severe	2(1.3)	-	1(0.7)
疲労	Overall	15(9.4)	5(3.0)	8(5.4)
	Mild	10(6.3)	3(1.8)	8(5.4)
	Moderate	5(3.1)	2(1.2)	-
	Severe	-	-	-
末梢性浮腫	Overall	5(3.1)	4(2.4)	7(4.7)
	Mild	3(1.9)	3(1.8)	3(2.0)
	Moderate	2(1.3)	1(0.6)	3(2.0)
	Severe	-	-	1(0.7)

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.1.1.5

表 2.7.4.7-付録-19　有害事象の程度別発現頻度（133 試験）（22/97）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=159)	 0.5 mg (N=164)	 1 mg (N=149)
一般・全身障害および投与部位の状態（続き）				
無力症	Overall	3(1.9)	4(2.4)	4(2.7)
	Mild	3(1.9)	2(1.2)	2(1.3)
	Moderate	-	2(1.2)	2(1.3)
	Severe	-	-	-
胸痛	Overall	4(2.5)	3(1.8)	2(1.3)
	Mild	1(0.6)	1(0.6)	1(0.7)
	Moderate	1(0.6)	2(1.2)	1(0.7)
	Severe	2(1.3)	-	-
歩行障害	Overall	3(1.9)	4(2.4)	1(0.7)
	Mild	-	2(1.2)	-
	Moderate	3(1.9)	2(1.2)	1(0.7)
	Severe	-	-	-
末梢腫脹	Overall	5(3.1)	2(1.2)	-
	Mild	2(1.3)	2(1.2)	-
	Moderate	3(1.9)	-	-
	Severe	-	-	-
発熱	Overall	2(1.3)	2(1.2)	1(0.7)
	Mild	2(1.3)	1(0.6)	1(0.7)
	Moderate	-	1(0.6)	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.1.1.5

表 2.7.4.7-付録-19　有害事象の程度別発現頻度（133 試験）（23/97）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=159)	 0.5 mg (N=164)	 1 mg (N=149)
一般・全身障害および投与部位の状態（続き）				
胸部不快感	Overall	2(1.3)	1(0.6)	1(0.7)
	Mild	-	-	-
	Moderate	2(1.3)	1(0.6)	1(0.7)
	Severe	-	-	-
倦怠感	Overall	2(1.3)	1(0.6)	1(0.7)
	Mild	1(0.6)	-	-
	Moderate	1(0.6)	1(0.6)	1(0.7)
	Severe	-	-	-
インフルエンザ様疾患	Overall	-	2(1.2)	1(0.7)
	Mild	-	1(0.6)	1(0.7)
	Moderate	-	1(0.6)	-
	Severe	-	-	-
悪寒	Overall	1(0.6)	1(0.6)	-
	Mild	-	1(0.6)	-
	Moderate	1(0.6)	-	-
	Severe	-	-	-
疼痛	Overall	1(0.6)	-	1(0.7)
	Mild	-	-	1(0.7)
	Moderate	1(0.6)	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.1.1.5

表 2.7.4.7-付録-19　有害事象の程度別発現頻度（133 試験）（24/97）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=159)	 0.5 mg (N=164)	 1 mg (N=149)
一般・全身障害および投与部位の状態（続き）				
口渇	Overall	1(0.6)	-	1(0.7)
	Mild	1(0.6)	-	1(0.7)
	Moderate	-	-	-
	Severe	-	-	-
腋窩痛	Overall	-	-	1(0.7)
	Mild	-	-	-
	Moderate	-	-	1(0.7)
	Severe	-	-	-
嚢胞破裂	Overall	1(0.6)	-	-
	Mild	1(0.6)	-	-
	Moderate	-	-	-
	Severe	-	-	-
ヘルニア	Overall	-	-	1(0.7)
	Mild	-	-	1(0.7)
	Moderate	-	-	-
	Severe	-	-	-
腫瘤	Overall	-	-	1(0.7)
	Mild	-	-	1(0.7)
	Moderate	-	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.1.1.5

表 2.7.4.7-付録-19　有害事象の程度別発現頻度（133 試験）（25/97）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=159)	 0.5 mg (N=164)	 1 mg (N=149)
肝胆道系障害	Overall	1(0.6)	1(0.6)	-
	Mild	-	-	-
	Moderate	-	1(0.6)	-
	Severe	1(0.6)	-	-
胆嚢炎	Overall	1(0.6)	1(0.6)	-
	Mild	-	-	-
	Moderate	-	1(0.6)	-
	Severe	1(0.6)	-	-
免疫系障害	Overall	2(1.3)	2(1.2)	1(0.7)
	Mild	1(0.6)	1(0.6)	-
	Moderate	1(0.6)	1(0.6)	1(0.7)
	Severe	-	-	-
季節性アレルギー	Overall	2(1.3)	2(1.2)	1(0.7)
	Mild	1(0.6)	1(0.6)	-
	Moderate	1(0.6)	1(0.6)	1(0.7)
	Severe	-	-	-
感染症および寄生虫症	Overall	46(28.9)	52(31.7)	48(32.2)
	Mild	25(15.7)	34(20.7)	33(22.1)
	Moderate	16(10.1)	15(9.1)	13(8.7)
	Severe	5(3.1)	3(1.8)	2(1.3)
尿路感染	Overall	16(10.1)	10(6.1)	15(10.1)
	Mild	10(6.3)	8(4.9)	12(8.1)
	Moderate	3(1.9)	2(1.2)	3(2.0)
	Severe	3(1.9)	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.1.1.5

表 2.7.4.7-付録-19　有害事象の程度別発現頻度（133 試験）（26/97）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=159)	 0.5 mg (N=164)	 1 mg (N=149)
感染症および寄生虫症（続き）				
鼻咽頭炎	Overall	9(5.7)	17(10.4)	7(4.7)
	Mild	6(3.8)	13(7.9)	5(3.4)
	Moderate	3(1.9)	4(2.4)	2(1.3)
	Severe	-	-	-
上気道感染	Overall	7(4.4)	8(4.9)	6(4.0)
	Mild	5(3.1)	7(4.3)	5(3.4)
	Moderate	2(1.3)	1(0.6)	1(0.7)
	Severe	-	-	-
細菌尿	Overall	2(1.3)	4(2.4)	3(2.0)
	Mild	1(0.6)	2(1.2)	3(2.0)
	Moderate	-	2(1.2)	-
	Severe	1(0.6)	-	-
副鼻腔炎	Overall	3(1.9)	3(1.8)	2(1.3)
	Mild	1(0.6)	1(0.6)	2(1.3)
	Moderate	2(1.3)	2(1.2)	-
	Severe	-	-	-
歯感染	Overall	2(1.3)	2(1.2)	1(0.7)
	Mild	1(0.6)	-	-
	Moderate	1(0.6)	2(1.2)	1(0.7)
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.1.1.5

表 2.7.4.7-付録-19　有害事象の程度別発現頻度（133 試験）（27/97）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=159)	 0.5 mg (N=164)	 1 mg (N=149)
感染症および寄生虫症（続き）				
ウイルス性胃腸炎	Overall	1(0.6)	1(0.6)	2(1.3)
	Mild	1(0.6)	1(0.6)	-
	Moderate	-	-	2(1.3)
	Severe	-	-	-
歯肉炎	Overall	-	1(0.6)	3(2.0)
	Mild	-	1(0.6)	3(2.0)
	Moderate	-	-	-
	Severe	-	-	-
気管支炎	Overall	1(0.6)	1(0.6)	1(0.7)
	Mild	-	-	-
	Moderate	1(0.6)	1(0.6)	1(0.7)
	Severe	-	-	-
蜂巣炎	Overall	1(0.6)	-	2(1.3)
	Mild	-	-	-
	Moderate	-	-	2(1.3)
	Severe	1(0.6)	-	-
皮膚真菌感染	Overall	2(1.3)	-	1(0.7)
	Mild	1(0.6)	-	1(0.7)
	Moderate	1(0.6)	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.1.1.5

表 2.7.4.7-付録-19　有害事象の程度別発現頻度（133 試験）（28/97）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=159)	 0.5 mg (N=164)	 1 mg (N=149)
感染症および寄生虫症（続き）				
肺炎	Overall	2(1.3)	1(0.6)	-
	Mild	-	-	-
	Moderate	1(0.6)	-	-
	Severe	1(0.6)	1(0.6)	-
術後創感染	Overall	-	1(0.6)	2(1.3)
	Mild	-	-	2(1.3)
	Moderate	-	-	-
	Severe	-	1(0.6)	-
歯膿瘍	Overall	2(1.3)	1(0.6)	-
	Mild	-	-	-
	Moderate	2(1.3)	1(0.6)	-
	Severe	-	-	-
耳感染	Overall	1(0.6)	-	1(0.7)
	Mild	1(0.6)	-	1(0.7)
	Moderate	-	-	-
	Severe	-	-	-
ヘリコバクター感染	Overall	-	2(1.2)	-
	Mild	-	2(1.2)	-
	Moderate	-	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.1.1.5

表 2.7.4.7-付録-19　有害事象の程度別発現頻度（133 試験）（29/97）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=159)	 0.5 mg (N=164)	 1 mg (N=149)
感染症および寄生虫症（続き）				
帯状疱疹	Overall	-	2(1.2)	-
	Mild	-	2(1.2)	-
	Moderate	-	-	-
	Severe	-	-	-
足部白癬	Overall	-	1(0.6)	1(0.7)
	Mild	-	1(0.6)	1(0.7)
	Moderate	-	-	-
	Severe	-	-	-
ウイルス感染	Overall	-	1(0.6)	1(0.7)
	Mild	-	-	-
	Moderate	-	1(0.6)	1(0.7)
	Severe	-	-	-
感染性関節炎	Overall	-	-	1(0.7)
	Mild	-	-	-
	Moderate	-	-	-
	Severe	-	-	1(0.7)
感染性滑液包炎	Overall	-	1(0.6)	-
	Mild	-	-	-
	Moderate	-	-	-
	Severe	-	1(0.6)	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.1.1.5

表 2.7.4.7-付録-19　有害事象の程度別発現頻度（133 試験）（30/97）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=159)	 0.5 mg (N=164)	 1 mg (N=149)
感染症および寄生虫症（続き）				
ブドウ球菌感染性滑液包炎	Overall	-	1(0.6)	-
	Mild	-	-	-
	Moderate	-	-	-
	Severe	-	1(0.6)	-
膀胱炎	Overall	1(0.6)	-	-
	Mild	1(0.6)	-	-
	Moderate	-	-	-
	Severe	-	-	-
出血性腸憩室炎	Overall	-	1(0.6)	-
	Mild	-	-	-
	Moderate	-	-	-
	Severe	-	1(0.6)	-
眼感染	Overall	1(0.6)	-	-
	Mild	1(0.6)	-	-
	Moderate	-	-	-
	Severe	-	-	-
真菌感染	Overall	1(0.6)	-	-
	Mild	1(0.6)	-	-
	Moderate	-	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.1.1.5

表 2.7.4.7-付録-19　有害事象の程度別発現頻度（133 試験）（31/97）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=159)	 0.5 mg (N=164)	 1 mg (N=149)
感染症および寄生虫症（続き）				
胃腸炎	Overall	1(0.6)	-	-
	Mild	1(0.6)	-	-
	Moderate	-	-	-
	Severe	-	-	-
ヘリコバクター性胃炎	Overall	-	1(0.6)	-
	Mild	-	-	-
	Moderate	-	1(0.6)	-
	Severe	-	-	-
単純ヘルペス	Overall	-	-	1(0.7)
	Mild	-	-	1(0.7)
	Moderate	-	-	-
	Severe	-	-	-
麦粒腫	Overall	-	-	1(0.7)
	Mild	-	-	1(0.7)
	Moderate	-	-	-
	Severe	-	-	-
膿痂疹	Overall	1(0.6)	-	-
	Mild	1(0.6)	-	-
	Moderate	-	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.1.1.5

表 2.7.4.7-付録-19　有害事象の程度別発現頻度（133 試験）（32/97）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=159)	 0.5 mg (N=164)	 1 mg (N=149)
感染症および寄生虫症（続き）				
感染性皮膚嚢腫	Overall	-	-	1(0.7)
	Mild	-	-	-
	Moderate	-	-	1(0.7)
	Severe	-	-	-
インフルエンザ	Overall	-	-	1(0.7)
	Mild	-	-	1(0.7)
	Moderate	-	-	-
	Severe	-	-	-
腎感染	Overall	1(0.6)	-	-
	Mild	1(0.6)	-	-
	Moderate	-	-	-
	Severe	-	-	-
限局性感染	Overall	1(0.6)	-	-
	Mild	-	-	-
	Moderate	1(0.6)	-	-
	Severe	-	-	-
爪感染	Overall	1(0.6)	-	-
	Mild	-	-	-
	Moderate	1(0.6)	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.1.1.5

表 2.7.4.7-付録-19　有害事象の程度別発現頻度（133 試験）（33/97）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=159)	 0.5 mg (N=164)	 1 mg (N=149)
感染症および寄生虫症（続き）				
外耳炎	Overall	-	1(0.6)	-
	Mild	-	-	-
	Moderate	-	1(0.6)	-
	Severe	-	-	-
術後膿瘍	Overall	1(0.6)	-	-
	Mild	-	-	-
	Moderate	1(0.6)	-	-
	Severe	-	-	-
腎盂腎炎	Overall	-	-	1(0.7)
	Mild	-	-	-
	Moderate	-	-	-
	Severe	-	-	1(0.7)
癜風	Overall	1(0.6)	-	-
	Mild	1(0.6)	-	-
	Moderate	-	-	-
	Severe	-	-	-
ウイルス性鼻炎	Overall	-	-	1(0.7)
	Mild	-	-	-
	Moderate	-	-	1(0.7)
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.1.1.5

表 2.7.4.7-付録-19　有害事象の程度別発現頻度（133 試験）（34/97）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=159)	 0.5 mg (N=164)	 1 mg (N=149)
感染症および寄生虫症（続き）				
創傷感染	Overall	-	1(0.6)	-
	Mild	-	1(0.6)	-
	Moderate	-	-	-
	Severe	-	-	-
傷害、中毒および処置合併症	Overall	28(17.6)	30(18.3)	34(22.8)
	Mild	13(8.2)	13(7.9)	14(9.4)
	Moderate	14(8.8)	16(9.8)	13(8.7)
	Severe	1(0.6)	1(0.6)	7(4.7)
転倒	Overall	13(8.2)	19(11.6)	16(10.7)
	Mild	3(1.9)	8(4.9)	8(5.4)
	Moderate	9(5.7)	11(6.7)	7(4.7)
	Severe	1(0.6)	-	1(0.7)
挫傷	Overall	2(1.3)	4(2.4)	6(4.0)
	Mild	2(1.3)	3(1.8)	5(3.4)
	Moderate	-	1(0.6)	1(0.7)
	Severe	-	-	-
裂傷	Overall	-	2(1.2)	2(1.3)
	Mild	-	-	1(0.7)
	Moderate	-	2(1.2)	1(0.7)
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.1.1.5

表 2.7.4.7-付録-19　有害事象の程度別発現頻度（133 試験）（35/97）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=159)	 0.5 mg (N=164)	 1 mg (N=149)
傷害、中毒および処置合併症（続き）				
靱帯捻挫	Overall	-	1(0.6)	3(2.0)
	Mild	-	1(0.6)	1(0.7)
	Moderate	-	-	1(0.7)
	Severe	-	-	1(0.7)
処置による疼痛	Overall	2(1.3)	-	2(1.3)
	Mild	1(0.6)	-	-
	Moderate	1(0.6)	-	1(0.7)
	Severe	-	-	1(0.7)
皮膚擦過傷	Overall	1(0.6)	2(1.2)	1(0.7)
	Mild	1(0.6)	1(0.6)	-
	Moderate	-	1(0.6)	1(0.7)
	Severe	-	-	-
足骨折	Overall	1(0.6)	-	2(1.3)
	Mild	1(0.6)	-	1(0.7)
	Moderate	-	-	1(0.7)
	Severe	-	-	-
四肢損傷	Overall	-	3(1.8)	-
	Mild	-	2(1.2)	-
	Moderate	-	1(0.6)	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]　Statistical Analysis Report (5.3.5.3-1) Table 2.1.1.5

表 2.7.4.7-付録-19　有害事象の程度別発現頻度（133 試験）（36/97）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=159)	 0.5 mg (N=164)	 1 mg (N=149)
傷害、中毒および処置合併症（続き）				
肉離れ	Overall	1(0.6)	2(1.2)	-
	Mild	-	2(1.2)	-
	Moderate	1(0.6)	-	-
	Severe	-	-	-
交通事故	Overall	-	2(1.2)	1(0.7)
	Mild	-	-	-
	Moderate	-	1(0.6)	1(0.7)
	Severe	-	1(0.6)	-
節足動物咬傷	Overall	-	-	2(1.3)
	Mild	-	-	1(0.7)
	Moderate	-	-	-
	Severe	-	-	1(0.7)
背部損傷	Overall	1(0.6)	-	1(0.7)
	Mild	-	-	1(0.7)
	Moderate	1(0.6)	-	-
	Severe	-	-	-
骨挫傷	Overall	-	-	2(1.3)
	Mild	-	-	1(0.7)
	Moderate	-	-	1(0.7)
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.1.1.5

表 2.7.4.7-付録-19　有害事象の程度別発現頻度（133 試験）（37/97）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=159)	 0.5 mg (N=164)	 1 mg (N=149)
傷害、中毒および処置合併症（続き）				
関節損傷	Overall	-	1(0.6)	1(0.7)
	Mild	-	1(0.6)	1(0.7)
	Moderate	-	-	-
	Severe	-	-	-
外傷後疼痛	Overall	-	1(0.6)	1(0.7)
	Mild	-	-	-
	Moderate	-	1(0.6)	-
	Severe	-	-	1(0.7)
術後創合併症	Overall	1(0.6)	-	1(0.7)
	Mild	1(0.6)	-	1(0.7)
	Moderate	-	-	-
	Severe	-	-	-
腱断裂	Overall	1(0.6)	-	1(0.7)
	Mild	1(0.6)	-	-
	Moderate	-	-	1(0.7)
	Severe	-	-	-
歯牙破折	Overall	1(0.6)	-	1(0.7)
	Mild	1(0.6)	-	-
	Moderate	-	-	1(0.7)
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.1.1.5

表 2.7.4.7-付録-19　有害事象の程度別発現頻度（133 試験）（38/97）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=159)	 0.5 mg (N=164)	 1 mg (N=149)
傷害、中毒および処置合併症（続き）				
外傷性血腫	Overall	-	-	2(1.3)
	Mild	-	-	1(0.7)
	Moderate	-	-	1(0.7)
	Severe	-	-	-
創傷	Overall	-	-	2(1.3)
	Mild	-	-	-
	Moderate	-	-	2(1.3)
	Severe	-	-	-
動脈損傷	Overall	1(0.6)	-	-
	Mild	-	-	-
	Moderate	-	-	-
	Severe	1(0.6)	-	-
軟骨損傷	Overall	-	1(0.6)	-
	Mild	-	-	-
	Moderate	-	1(0.6)	-
	Severe	-	-	-
白内障手術合併症	Overall	1(0.6)	-	-
	Mild	-	-	-
	Moderate	1(0.6)	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.1.1.5

表 2.7.4.7-付録-19　有害事象の程度別発現頻度（133 試験）（39/97）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=159)	 0.5 mg (N=164)	 1 mg (N=149)
傷害、中毒および処置合併症（続き）				
頚椎骨折	Overall	-	1(0.6)	-
	Mild	-	-	-
	Moderate	-	-	-
	Severe	-	1(0.6)	-
眼部化学熱傷	Overall	-	-	1(0.7)
	Mild	-	-	1(0.7)
	Moderate	-	-	-
	Severe	-	-	-
上顎炎	Overall	-	1(0.6)	-
	Mild	-	-	-
	Moderate	-	1(0.6)	-
	Severe	-	-	-
眼挫傷	Overall	-	1(0.6)	-
	Mild	-	-	-
	Moderate	-	1(0.6)	-
	Severe	-	-	-
顔面損傷	Overall	-	1(0.6)	-
	Mild	-	-	-
	Moderate	-	1(0.6)	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.1.1.5

表 2.7.4.7-付録-19　有害事象の程度別発現頻度（133 試験）（40/97）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=159)	 0.5 mg (N=164)	 1 mg (N=149)
傷害、中毒および処置合併症（続き）				
手骨折	Overall	-	1(0.6)	-
	Mild	-	-	-
	Moderate	-	1(0.6)	-
	Severe	-	-	-
股関節部骨折	Overall	-	-	1(0.7)
	Mild	-	-	-
	Moderate	-	-	-
	Severe	-	-	1(0.7)
切開部位痛	Overall	-	1(0.6)	-
	Mild	-	-	-
	Moderate	-	1(0.6)	-
	Severe	-	-	-
関節脱臼	Overall	1(0.6)	-	-
	Mild	-	-	-
	Moderate	-	-	-
	Severe	1(0.6)	-	-
靱帯損傷	Overall	-	1(0.6)	-
	Mild	-	-	-
	Moderate	-	1(0.6)	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]. Statistical Analysis Report (5.3.5.3-1) Table 2.1.1.5

表 2.7.4.7-付録-19　有害事象の程度別発現頻度（133 試験）（41/97）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=159)	 0.5 mg (N=164)	 1 mg (N=149)
傷害、中毒および処置合併症（続き）				
靱帯断裂	Overall	-	-	1(0.7)
	Mild	-	-	-
	Moderate	-	-	1(0.7)
	Severe	-	-	-
半月板損傷	Overall	-	-	1(0.7)
	Mild	-	-	-
	Moderate	-	-	-
	Severe	-	-	1(0.7)
筋断裂	Overall	1(0.6)	-	-
	Mild	-	-	-
	Moderate	1(0.6)	-	-
	Severe	-	-	-
眼窩周囲出血	Overall	-	-	1(0.7)
	Mild	-	-	-
	Moderate	-	-	1(0.7)
	Severe	-	-	-
処置後不快感	Overall	-	1(0.6)	-
	Mild	-	-	-
	Moderate	-	1(0.6)	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.1.1.5

表 2.7.4.7-付録-19　有害事象の程度別発現頻度（133 試験）（42/97）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=159)	 0.5 mg (N=164)	 1 mg (N=149)
傷害、中毒および処置合併症（続き）				
処置後血腫	Overall	1(0.6)	-	-
	Mild	1(0.6)	-	-
	Moderate	-	-	-
	Severe	-	-	-
処置によるめまい	Overall	1(0.6)	-	-
	Mild	1(0.6)	-	-
	Moderate	-	-	-
	Severe	-	-	-
処置による気胸	Overall	-	-	1(0.7)
	Mild	-	-	-
	Moderate	-	-	-
	Severe	-	-	1(0.7)
肋骨骨折	Overall	1(0.6)	-	-
	Mild	1(0.6)	-	-
	Moderate	-	-	-
	Severe	-	-	-
引っかき傷	Overall	-	-	1(0.7)
	Mild	-	-	1(0.7)
	Moderate	-	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]. Statistical Analysis Report (5.3.5.3-1) Table 2.1.1.5

表 2.7.4.7-付録-19　有害事象の程度別発現頻度（133 試験）（43/97）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=159)	 0.5 mg (N=164)	 1 mg (N=149)
傷害、中毒および処置合併症（続き）				
熱傷	Overall	1(0.6)	-	-
	Mild	-	-	-
	Moderate	1(0.6)	-	-
	Severe	-	-	-
術後尿閉	Overall	-	1(0.6)	-
	Mild	-	1(0.6)	-
	Moderate	-	-	-
	Severe	-	-	-
手首関節骨折	Overall	-	-	1(0.7)
	Mild	-	-	-
	Moderate	-	-	1(0.7)
	Severe	-	-	-
臨床検査	Overall	21(13.2)	19(11.6)	26(17.4)
	Mild	17(10.7)	15(9.1)	20(13.4)
	Moderate	3(1.9)	3(1.8)	6(4.0)
	Severe	1(0.6)	1(0.6)	-
体重減少	Overall	4(2.5)	4(2.4)	14(9.4)
	Mild	2(1.3)	2(1.2)	9(6.0)
	Moderate	1(0.6)	1(0.6)	5(3.4)
	Severe	1(0.6)	1(0.6)	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.1.1.5

表 2.7.4.7-付録-19　有害事象の程度別発現頻度（133 試験）（44/97）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=159)	 0.5 mg (N=164)	 1 mg (N=149)
臨床検査（続き）				
血圧上昇	Overall	1(0.6)	2(1.2)	1(0.7)
	Mild	1(0.6)	2(1.2)	1(0.7)
	Moderate	-	-	-
	Severe	-	-	-
ヘマトクリット減少	Overall	2(1.3)	1(0.6)	1(0.7)
	Mild	1(0.6)	1(0.6)	1(0.7)
	Moderate	1(0.6)	-	-
	Severe	-	-	-
尿中白血球陽性	Overall	-	2(1.2)	2(1.3)
	Mild	-	2(1.2)	2(1.3)
	Moderate	-	-	-
	Severe	-	-	-
ヘモグロビン減少	Overall	2(1.3)	1(0.6)	-
	Mild	1(0.6)	1(0.6)	-
	Moderate	1(0.6)	-	-
	Severe	-	-	-
白血球数増加	Overall	2(1.3)	-	1(0.7)
	Mild	2(1.3)	-	1(0.7)
	Moderate	-	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.1.1.5

表 2.7.4.7-付録-19　有害事象の程度別発現頻度（133 試験）（45/97）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=159)	 0.5 mg (N=164)	 1 mg (N=149)
臨床検査（続き）				
血中カルシウム増加	Overall	-	1(0.6)	1(0.7)
	Mild	-	1(0.6)	1(0.7)
	Moderate	-	-	-
	Severe	-	-	-
血中コレステロール増加	Overall	1(0.6)	-	1(0.7)
	Mild	1(0.6)	-	1(0.7)
	Moderate	-	-	-
	Severe	-	-	-
血中カリウム増加	Overall	1(0.6)	1(0.6)	-
	Mild	1(0.6)	-	-
	Moderate	-	1(0.6)	-
	Severe	-	-	-
尿中血陽性	Overall	1(0.6)	1(0.6)	-
	Mild	1(0.6)	1(0.6)	-
	Moderate	-	-	-
	Severe	-	-	-
心電図T波振幅減少	Overall	-	-	2(1.3)
	Mild	-	-	2(1.3)
	Moderate	-	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]　Statistical Analysis Report (5.3.5.3-1) Table 2.1.1.5

表 2.7.4.7-付録-19　有害事象の程度別発現頻度（133 試験）（46/97）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=159)	 0.5 mg (N=164)	 1 mg (N=149)
臨床検査（続き）				
平均赤血球容積増加	Overall	2(1.3)	-	-
	Mild	2(1.3)	-	-
	Moderate	-	-	-
	Severe	-	-	-
赤血球数減少	Overall	1(0.6)	1(0.6)	-
	Mild	-	1(0.6)	-
	Moderate	1(0.6)	-	-
	Severe	-	-	-
尿検査異常	Overall	1(0.6)	1(0.6)	-
	Mild	1(0.6)	1(0.6)	-
	Moderate	-	-	-
	Severe	-	-	-
尿中ケトン体陽性	Overall	-	1(0.6)	1(0.7)
	Mild	-	1(0.6)	1(0.7)
	Moderate	-	-	-
	Severe	-	-	-
体重増加	Overall	1(0.6)	-	1(0.7)
	Mild	1(0.6)	-	1(0.7)
	Moderate	-	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.1.1.5

表 2.7.4.7-付録-19　有害事象の程度別発現頻度（133 試験）（47/97）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=159)	 0.5 mg (N=164)	 1 mg (N=149)
臨床検査（続き）				
白血球数減少	Overall	-	1(0.6)	1(0.7)
	Mild	-	1(0.6)	1(0.7)
	Moderate	-	-	-
	Severe	-	-	-
細菌検査陽性	Overall	-	-	1(0.7)
	Mild	-	-	1(0.7)
	Moderate	-	-	-
	Severe	-	-	-
血中ブドウ糖増加	Overall	-	1(0.6)	-
	Mild	-	1(0.6)	-
	Moderate	-	-	-
	Severe	-	-	-
血中乳酸脱水素酵素増加	Overall	-	-	1(0.7)
	Mild	-	-	1(0.7)
	Moderate	-	-	-
	Severe	-	-	-
血中カリウム減少	Overall	-	-	1(0.7)
	Mild	-	-	1(0.7)
	Moderate	-	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]　Statistical Analysis Report (5.3.5.3-1) Table 2.1.1.5

表 2.7.4.7-付録-19　有害事象の程度別発現頻度（133 試験）（48/97）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=159)	 0.5 mg (N=164)	 1 mg (N=149)
臨床検査（続き）				
拡張期血圧上昇	Overall	-	-	1(0.7)
	Mild	-	-	1(0.7)
	Moderate	-	-	-
	Severe	-	-	-
血中尿素増加	Overall	-	-	1(0.7)
	Mild	-	-	1(0.7)
	Moderate	-	-	-
	Severe	-	-	-
呼吸音異常	Overall	1(0.6)	-	-
	Mild	1(0.6)	-	-
	Moderate	-	-	-
	Severe	-	-	-
心雑音	Overall	-	-	1(0.7)
	Mild	-	-	1(0.7)
	Moderate	-	-	-
	Severe	-	-	-
頚動脈雑音	Overall	1(0.6)	-	-
	Mild	1(0.6)	-	-
	Moderate	-	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.1.1.5

表 2.7.4.7-付録-19　有害事象の程度別発現頻度（133 試験）（49/97）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=159)	 0.5 mg (N=164)	 1 mg (N=149)
臨床検査（続き）				
心エコー像異常	Overall	1(0.6)	-	-
	Mild	1(0.6)	-	-
	Moderate	-	-	-
	Severe	-	-	-
心電図ＳＴ－Ｔ変化	Overall	-	1(0.6)	-
	Mild	-	-	-
	Moderate	-	1(0.6)	-
	Severe	-	-	-
心電図異常	Overall	-	-	1(0.7)
	Mild	-	-	-
	Moderate	-	-	1(0.7)
	Severe	-	-	-
γ－グルタミルトランスフェラーゼ増加	Overall	-	1(0.6)	-
	Mild	-	1(0.6)	-
	Moderate	-	-	-
	Severe	-	-	-
心拍数増加	Overall	-	1(0.6)	-
	Mild	-	1(0.6)	-
	Moderate	-	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]. Statistical Analysis Report (5.3.5.3-1) Table 2.1.1.5

表 2.7.4.7-付録-19　有害事象の程度別発現頻度（133 試験）（50/97）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=159)	 0.5 mg (N=164)	 1 mg (N=149)
臨床検査（続き）				
眼圧上昇	Overall	1(0.6)	-	-
	Mild	-	-	-
	Moderate	1(0.6)	-	-
	Severe	-	-	-
単球数減少	Overall	-	1(0.6)	-
	Mild	-	1(0.6)	-
	Moderate	-	-	-
	Severe	-	-	-
好中球数増加	Overall	1(0.6)	-	-
	Mild	1(0.6)	-	-
	Moderate	-	-	-
	Severe	-	-	-
足脈拍減少	Overall	1(0.6)	-	-
	Mild	1(0.6)	-	-
	Moderate	-	-	-
	Severe	-	-	-
総蛋白増加	Overall	-	1(0.6)	-
	Mild	-	1(0.6)	-
	Moderate	-	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]. Statistical Analysis Report (5.3.5.3-1) Table 2.1.1.5

表 2.7.4.7-付録-19　有害事象の程度別発現頻度（133 試験）（51/97）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=159)	 0.5 mg (N=164)	 1 mg (N=149)
臨床検査（続き）				
赤血球数異常	Overall	1(0.6)	-	-
	Mild	1(0.6)	-	-
	Moderate	-	-	-
	Severe	-	-	-
代謝および栄養障害	Overall	6(3.8)	11(6.7)	11(7.4)
	Mild	6(3.8)	8(4.9)	8(5.4)
	Moderate	-	3(1.8)	3(2.0)
	Severe	-	-	-
食欲減退	Overall	1(0.6)	3(1.8)	8(5.4)
	Mild	1(0.6)	2(1.2)	6(4.0)
	Moderate	-	1(0.6)	2(1.3)
	Severe	-	-	-
高コレステロール血症	Overall	2(1.3)	4(2.4)	-
	Mild	2(1.3)	3(1.8)	-
	Moderate	-	1(0.6)	-
	Severe	-	-	-
脱水	Overall	-	1(0.6)	1(0.7)
	Mild	-	-	-
	Moderate	-	1(0.6)	1(0.7)
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]　Statistical Analysis Report (5.3.5.3-1) Table 2.1.1.5

表 2.7.4.7-付録-19　有害事象の程度別発現頻度（133 試験）（52/97）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=159)	 0.5 mg (N=164)	 1 mg (N=149)
代謝および栄養障害（続き）				
高リン酸塩血症	Overall	-	1(0.6)	1(0.7)
	Mild	-	1(0.6)	1(0.7)
	Moderate	-	-	-
	Severe	-	-	-
糖尿病性ケトアシドーシス	Overall	1(0.6)	-	-
	Mild	1(0.6)	-	-
	Moderate	-	-	-
	Severe	-	-	-
体液貯留	Overall	1(0.6)	-	-
	Mild	1(0.6)	-	-
	Moderate	-	-	-
	Severe	-	-	-
葉酸欠乏	Overall	1(0.6)	-	-
	Mild	1(0.6)	-	-
	Moderate	-	-	-
	Severe	-	-	-
耐糖能障害	Overall	-	1(0.6)	-
	Mild	-	1(0.6)	-
	Moderate	-	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]. Statistical Analysis Report (5.3.5.3-1) Table 2.1.1.5

表 2.7.4.7-付録-19　有害事象の程度別発現頻度（133 試験）（53/97）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=159)	 0.5 mg (N=164)	 1 mg (N=149)
代謝および栄養障害（続き）				
高脂血症	Overall	-	-	1(0.7)
	Mild	-	-	1(0.7)
	Moderate	-	-	-
	Severe	-	-	-
低リン酸血症	Overall	-	1(0.6)	-
	Mild	-	1(0.6)	-
	Moderate	-	-	-
	Severe	-	-	-
ビタミンＢ１２欠乏	Overall	1(0.6)	-	-
	Mild	1(0.6)	-	-
	Moderate	-	-	-
	Severe	-	-	-
筋骨格系および結合組織障害	Overall	42(26.4)	37(22.6)	38(25.5)
	Mild	19(11.9)	13(7.9)	19(12.8)
	Moderate	19(11.9)	21(12.8)	13(8.7)
	Severe	4(2.5)	3(1.8)	6(4.0)
背部痛	Overall	12(7.5)	7(4.3)	9(6.0)
	Mild	5(3.1)	2(1.2)	2(1.3)
	Moderate	6(3.8)	4(2.4)	6(4.0)
	Severe	1(0.6)	1(0.6)	1(0.7)

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.1.1.5

表 2.7.4.7-付録-19　有害事象の程度別発現頻度（133 試験）（54/97）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=159)	 0.5 mg (N=164)	 1 mg (N=149)
筋骨格系および結合組織障害（続き）				
関節痛	Overall	3(1.9)	8(4.9)	7(4.7)
	Mild	-	5(3.0)	3(2.0)
	Moderate	2(1.3)	3(1.8)	3(2.0)
	Severe	1(0.6)	-	1(0.7)
四肢痛	Overall	5(3.1)	3(1.8)	6(4.0)
	Mild	3(1.9)	2(1.2)	4(2.7)
	Moderate	2(1.3)	1(0.6)	1(0.7)
	Severe	-	-	1(0.7)
筋痙縮	Overall	5(3.1)	5(3.0)	2(1.3)
	Mild	3(1.9)	1(0.6)	2(1.3)
	Moderate	2(1.3)	4(2.4)	-
	Severe	-	-	-
筋骨格痛	Overall	2(1.3)	2(1.2)	5(3.4)
	Mild	1(0.6)	1(0.6)	5(3.4)
	Moderate	1(0.6)	-	-
	Severe	-	1(0.6)	-
関節炎	Overall	2(1.3)	4(2.4)	2(1.3)
	Mild	2(1.3)	-	1(0.7)
	Moderate	-	4(2.4)	-
	Severe	-	-	1(0.7)

有害事象名：MedDRA/J ver[redacted]　Statistical Analysis Report (5.3.5.3-1) Table 2.1.1.5

表 2.7.4.7-付録-19　有害事象の程度別発現頻度（133 試験）（55/97）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=159)	 0.5 mg (N=164)	 1 mg (N=149)
筋骨格系および結合組織障害（続き）				
関節腫脹	Overall	4(2.5)	1(0.6)	2(1.3)
	Mild	3(1.9)	1(0.6)	1(0.7)
	Moderate	1(0.6)	-	1(0.7)
	Severe	-	-	-
筋肉痛	Overall	4(2.5)	2(1.2)	1(0.7)
	Mild	3(1.9)	1(0.6)	-
	Moderate	1(0.6)	1(0.6)	1(0.7)
	Severe	-	-	-
筋力低下	Overall	-	3(1.8)	3(2.0)
	Mild	-	1(0.6)	2(1.3)
	Moderate	-	2(1.2)	1(0.7)
	Severe	-	-	-
頚部痛	Overall	2(1.3)	-	4(2.7)
	Mild	2(1.3)	-	3(2.0)
	Moderate	-	-	-
	Severe	-	-	1(0.7)
筋骨格硬直	Overall	2(1.3)	2(1.2)	-
	Mild	2(1.3)	1(0.6)	-
	Moderate	-	1(0.6)	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]. Statistical Analysis Report (5.3.5.3-1) Table 2.1.1.5

表 2.7.4.7-付録-19　有害事象の程度別発現頻度（133 試験）（56/97）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=159)	 0.5 mg (N=164)	 1 mg (N=149)
筋骨格系および結合組織障害（続き）				
骨粗鬆症	Overall	2(1.3)	1(0.6)	1(0.7)
	Mild	-	-	1(0.7)
	Moderate	1(0.6)	-	-
	Severe	1(0.6)	1(0.6)	-
筋骨格不快感	Overall	2(1.3)	1(0.6)	-
	Mild	1(0.6)	-	-
	Moderate	1(0.6)	1(0.6)	-
	Severe	-	-	-
滑液包炎	Overall	-	-	2(1.3)
	Mild	-	-	1(0.7)
	Moderate	-	-	1(0.7)
	Severe	-	-	-
関節硬直	Overall	2(1.3)	-	-
	Mild	-	-	-
	Moderate	2(1.3)	-	-
	Severe	-	-	-
筋固縮	Overall	1(0.6)	-	1(0.7)
	Mild	-	-	1(0.7)
	Moderate	1(0.6)	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]. Statistical Analysis Report (5.3.5.3-1) Table 2.1.1.5

表 2.7.4.7-付録-19　有害事象の程度別発現頻度（133 試験）（57/97）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=159)	 0.5 mg (N=164)	 1 mg (N=149)
筋骨格系および結合組織障害（続き）				
筋骨格系胸痛	Overall	-	-	2(1.3)
	Mild	-	-	-
	Moderate	-	-	1(0.7)
	Severe	-	-	1(0.7)
横紋筋融解症	Overall	-	2(1.2)	-
	Mild	-	-	-
	Moderate	-	2(1.2)	-
	Severe	-	-	-
腱炎	Overall	-	2(1.2)	-
	Mild	-	1(0.6)	-
	Moderate	-	1(0.6)	-
	Severe	-	-	-
外骨腫	Overall	-	1(0.6)	-
	Mild	-	-	-
	Moderate	-	1(0.6)	-
	Severe	-	-	-
足変形	Overall	1(0.6)	-	-
	Mild	-	-	-
	Moderate	-	-	-
	Severe	1(0.6)	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.1.1.5

表 2.7.4.7-付録-19　有害事象の程度別発現頻度（133 試験）（58/97）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=159)	 0.5 mg (N=164)	 1 mg (N=149)
筋骨格系および結合組織障害（続き）				
運動性低下	Overall	1(0.6)	-	-
	Mild	-	-	-
	Moderate	1(0.6)	-	-
	Severe	-	-	-
変形性関節症	Overall	-	-	1(0.7)
	Mild	-	-	-
	Moderate	-	-	1(0.7)
	Severe	-	-	-
骨減少症	Overall	-	1(0.6)	-
	Mild	-	1(0.6)	-
	Moderate	-	-	-
	Severe	-	-	-
顎痛	Overall	1(0.6)	-	-
	Mild	-	-	-
	Moderate	1(0.6)	-	-
	Severe	-	-	-
足底筋膜炎	Overall	-	1(0.6)	-
	Mild	-	-	-
	Moderate	-	1(0.6)	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.1.1.5

表 2.7.4.7-付録-19　有害事象の程度別発現頻度（133 試験）（59/97）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=159)	 0.5 mg (N=164)	 1 mg (N=149)
筋骨格系および結合組織障害（続き）				
側弯症	Overall	-	1(0.6)	-
	Mild	-	1(0.6)	-
	Moderate	-	-	-
	Severe	-	-	-
脊柱管狭窄症	Overall	1(0.6)	-	-
	Mild	-	-	-
	Moderate	1(0.6)	-	-
	Severe	-	-	-
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	Overall	11(6.9)	12(7.3)	12(8.1)
	Mild	6(3.8)	3(1.8)	5(3.4)
	Moderate	5(3.1)	8(4.9)	5(3.4)
	Severe	-	1(0.6)	2(1.3)
基底細胞癌	Overall	4(2.5)	7(4.3)	1(0.7)
	Mild	2(1.3)	2(1.2)	1(0.7)
	Moderate	2(1.3)	5(3.0)	-
	Severe	-	-	-
メラノサイト性母斑	Overall	1(0.6)	2(1.2)	1(0.7)
	Mild	1(0.6)	-	-
	Moderate	-	1(0.6)	1(0.7)
	Severe	-	1(0.6)	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.1.1.5

表 2.7.4.7-付録-19　有害事象の程度別発現頻度（133 試験）（60/97）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=159)	 0.5 mg (N=164)	 1 mg (N=149)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）（続き）				
脂漏性角化症	Overall	2(1.3)	1(0.6)	1(0.7)
	Mild	2(1.3)	1(0.6)	1(0.7)
	Moderate	-	-	-
	Severe	-	-	-
皮膚有棘細胞癌	Overall	1(0.6)	1(0.6)	2(1.3)
	Mild	-	-	-
	Moderate	1(0.6)	1(0.6)	1(0.7)
	Severe	-	-	1(0.7)
線維性組織球腫	Overall	2(1.3)	-	-
	Mild	2(1.3)	-	-
	Moderate	-	-	-
	Severe	-	-	-
悪性黒色腫	Overall	-	1(0.6)	1(0.7)
	Mild	-	-	-
	Moderate	-	1(0.6)	-
	Severe	-	-	1(0.7)
扁平上皮癌	Overall	-	-	2(1.3)
	Mild	-	-	1(0.7)
	Moderate	-	-	1(0.7)
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.1.1.5

表 2.7.4.7-付録-19　有害事象の程度別発現頻度（133 試験）（61/97）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=159)	 0.5 mg (N=164)	 1 mg (N=149)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）（続き）				
棘細胞腫	Overall	1(0.6)	-	-
	Mild	1(0.6)	-	-
	Moderate	-	-	-
	Severe	-	-	-
アクロコルドン	Overall	-	-	1(0.7)
	Mild	-	-	1(0.7)
	Moderate	-	-	-
	Severe	-	-	-
膀胱移行上皮癌	Overall	-	-	1(0.7)
	Mild	-	-	-
	Moderate	-	-	1(0.7)
	Severe	-	-	-
乳癌	Overall	1(0.6)	-	-
	Mild	-	-	-
	Moderate	1(0.6)	-	-
	Severe	-	-	-
結腸癌	Overall	1(0.6)	-	-
	Mild	-	-	-
	Moderate	1(0.6)	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.1.1.5

表 2.7.4.7-付録-19　有害事象の程度別発現頻度（133 試験）（62/97）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=159)	 0.5 mg (N=164)	 1 mg (N=149)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）（続き）				
異形成母斑	Overall	-	-	1(0.7)
	Mild	-	-	-
	Moderate	-	-	1(0.7)
	Severe	-	-	-
表皮内悪性黒色腫	Overall	-	-	1(0.7)
	Mild	-	-	1(0.7)
	Moderate	-	-	-
	Severe	-	-	-
単クローン性免疫グロブリン血症	Overall	1(0.6)	-	-
	Mild	1(0.6)	-	-
	Moderate	-	-	-
	Severe	-	-	-
前立腺癌	Overall	-	1(0.6)	-
	Mild	-	-	-
	Moderate	-	1(0.6)	-
	Severe	-	-	-
神経系障害	Overall	70(44.0)	73(44.5)	76(51.0)
	Mild	32(20.1)	28(17.1)	35(23.5)
	Moderate	31(19.5)	39(23.8)	31(20.8)
	Severe	7(4.4)	6(3.7)	10(6.7)

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.1.1.5

表 2.7.4.7-付録-19　有害事象の程度別発現頻度（133 試験）（63/97）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=159)	 0.5 mg (N=164)	 1 mg (N=149)
神経系障害（続き）				
ジスキネジア	Overall	15(9.4)	29(17.7)	27(18.1)
	Mild	7(4.4)	12(7.3)	11(7.4)
	Moderate	8(5.0)	14(8.5)	12(8.1)
	Severe	-	3(1.8)	4(2.7)
頭痛	Overall	15(9.4)	12(7.3)	17(11.4)
	Mild	10(6.3)	7(4.3)	12(8.1)
	Moderate	4(2.5)	5(3.0)	5(3.4)
	Severe	1(0.6)	-	-
浮動性めまい	Overall	14(8.8)	15(9.1)	13(8.7)
	Mild	11(6.9)	9(5.5)	10(6.7)
	Moderate	3(1.9)	6(3.7)	3(2.0)
	Severe	-	-	-
傾眠	Overall	4(2.5)	7(4.3)	9(6.0)
	Mild	2(1.3)	2(1.2)	3(2.0)
	Moderate	2(1.3)	5(3.0)	5(3.4)
	Severe	-	-	1(0.7)
平衡障害	Overall	1(0.6)	10(6.1)	5(3.4)
	Mild	-	6(3.7)	1(0.7)
	Moderate	1(0.6)	4(2.4)	4(2.7)
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.1.1.5

表 2.7.4.7-付録-19　有害事象の程度別発現頻度（133 試験）（64/97）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=159)	 0.5 mg (N=164)	 1 mg (N=149)
神経系障害（続き）				
ジストニア	Overall	2(1.3)	4(2.4)	4(2.7)
	Mild	-	1(0.6)	-
	Moderate	2(1.3)	3(1.8)	4(2.7)
	Severe	-	-	-
振戦	Overall	5(3.1)	3(1.8)	2(1.3)
	Mild	2(1.3)	2(1.2)	1(0.7)
	Moderate	3(1.9)	1(0.6)	1(0.7)
	Severe	-	-	-
感覚鈍麻	Overall	2(1.3)	2(1.2)	5(3.4)
	Mild	2(1.3)	2(1.2)	3(2.0)
	Moderate	-	-	1(0.7)
	Severe	-	-	1(0.7)
錯感覚	Overall	2(1.3)	3(1.8)	4(2.7)
	Mild	-	1(0.6)	1(0.7)
	Moderate	2(1.3)	2(1.2)	3(2.0)
	Severe	-	-	-
体位性めまい	Overall	1(0.6)	4(2.4)	3(2.0)
	Mild	1(0.6)	3(1.8)	2(1.3)
	Moderate	-	1(0.6)	1(0.7)
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]. Statistical Analysis Report (5.3.5.3-1) Table 2.1.1.5

表 2.7.4.7-付録-19　有害事象の程度別発現頻度（133 試験）（65/97）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=159)	 0.5 mg (N=164)	 1 mg (N=149)
神経系障害（続き）				
パーキンソニズム	Overall	3(1.9)	2(1.2)	2(1.3)
	Mild	2(1.3)	-	-
	Moderate	1(0.6)	1(0.6)	1(0.7)
	Severe	-	1(0.6)	1(0.7)
手根管症候群	Overall	-	1(0.6)	5(3.4)
	Mild	-	1(0.6)	3(2.0)
	Moderate	-	-	2(1.3)
	Severe	-	-	-
オンオフ現象	Overall	4(2.5)	1(0.6)	-
	Mild	1(0.6)	-	-
	Moderate	3(1.9)	-	-
	Severe	-	1(0.6)	-
パーキンソン病	Overall	2(1.3)	2(1.2)	-
	Mild	1(0.6)	-	-
	Moderate	1(0.6)	2(1.2)	-
	Severe	-	-	-
すくみ現象	Overall	-	-	3(2.0)
	Mild	-	-	2(1.3)
	Moderate	-	-	1(0.7)
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]　Statistical Analysis Report (5.3.5.3-1) Table 2.1.1.5

表 2.7.4.7-付録-19　有害事象の程度別発現頻度（133 試験）（66/97）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=159)	 0.5 mg (N=164)	 1 mg (N=149)
神経系障害（続き）				
嗜眠	Overall	2(1.3)	-	1(0.7)
	Mild	1(0.6)	-	1(0.7)
	Moderate	-	-	-
	Severe	1(0.6)	-	-
記憶障害	Overall	-	2(1.2)	1(0.7)
	Mild	-	-	1(0.7)
	Moderate	-	2(1.2)	-
	Severe	-	-	-
片頭痛	Overall	2(1.3)	1(0.6)	-
	Mild	-	-	-
	Moderate	-	1(0.6)	-
	Severe	2(1.3)	-	-
下肢静止不能症候群	Overall	1(0.6)	1(0.6)	1(0.7)
	Mild	-	-	1(0.7)
	Moderate	1(0.6)	1(0.6)	-
	Severe	-	-	-
失神	Overall	1(0.6)	1(0.6)	1(0.7)
	Mild	-	-	1(0.7)
	Moderate	-	1(0.6)	-
	Severe	1(0.6)	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.1.1.5

表 2.7.4.7-付録-19　有害事象の程度別発現頻度（133 試験）（67/97）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=159)	 0.5 mg (N=164)	 1 mg (N=149)
神経系障害（続き）				
脳血管発作	Overall	-	1(0.6)	1(0.7)
	Mild	-	-	-
	Moderate	-	-	-
	Severe	-	1(0.6)	1(0.7)
よだれ	Overall	-	1(0.6)	1(0.7)
	Mild	-	-	1(0.7)
	Moderate	-	1(0.6)	-
	Severe	-	-	-
異常感覚	Overall	-	2(1.2)	-
	Mild	-	1(0.6)	-
	Moderate	-	1(0.6)	-
	Severe	-	-	-
坐骨神経痛	Overall	2(1.3)	-	-
	Mild	-	-	-
	Moderate	2(1.3)	-	-
	Severe	-	-	-
健忘	Overall	-	-	1(0.7)
	Mild	-	-	-
	Moderate	-	-	1(0.7)
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.1.1.5

表 2.7.4.7-付録-19　有害事象の程度別発現頻度（133 試験）（68/97）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=159)	 0.5 mg (N=164)	 1 mg (N=149)
神経系障害（続き）				
自律神経失調	Overall	-	-	1(0.7)
	Mild	-	-	1(0.7)
	Moderate	-	-	-
	Severe	-	-	-
運動緩慢	Overall	-	-	1(0.7)
	Mild	-	-	1(0.7)
	Moderate	-	-	-
	Severe	-	-	-
脳幹卒中	Overall	-	-	1(0.7)
	Mild	-	-	-
	Moderate	-	-	-
	Severe	-	-	1(0.7)
認知障害	Overall	1(0.6)	-	-
	Mild	1(0.6)	-	-
	Moderate	-	-	-
	Severe	-	-	-
構語障害	Overall	-	-	1(0.7)
	Mild	-	-	-
	Moderate	-	-	-
	Severe	-	-	1(0.7)

有害事象名：MedDRA/J ver[redacted]. Statistical Analysis Report (5.3.5.3-1) Table 2.1.1.5

表 2.7.4.7-付録-19　有害事象の程度別発現頻度（133 試験）（69/97）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=159)	 0.5 mg (N=164)	 1 mg (N=149)
神経系障害（続き）				
味覚異常	Overall	-	-	1(0.7)
	Mild	-	-	1(0.7)
	Moderate	-	-	-
	Severe	-	-	-
伸展性足底反応	Overall	-	1(0.6)	-
	Mild	-	1(0.6)	-
	Moderate	-	-	-
	Severe	-	-	-
しかめ面	Overall	1(0.6)	-	-
	Mild	1(0.6)	-	-
	Moderate	-	-	-
	Severe	-	-	-
頭部不快感	Overall	-	1(0.6)	-
	Mild	-	-	-
	Moderate	-	1(0.6)	-
	Severe	-	-	-
不全片麻痺	Overall	1(0.6)	-	-
	Mild	-	-	-
	Moderate	-	-	-
	Severe	1(0.6)	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.1.1.5

表 2.7.4.7-付録-19　有害事象の程度別発現頻度（133 試験）（70/97）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=159)	 0.5 mg (N=164)	 1 mg (N=149)
神経系障害（続き）				
意識消失	Overall	-	1(0.6)	-
	Mild	-	-	-
	Moderate	-	1(0.6)	-
	Severe	-	-	-
精神的機能障害	Overall	1(0.6)	-	-
	Mild	-	-	-
	Moderate	1(0.6)	-	-
	Severe	-	-	-
運動障害	Overall	1(0.6)	-	-
	Mild	-	-	-
	Moderate	1(0.6)	-	-
	Severe	-	-	-
不随意性筋収縮	Overall	-	-	1(0.7)
	Mild	-	-	1(0.7)
	Moderate	-	-	-
	Severe	-	-	-
ミオクローヌス	Overall	1(0.6)	-	-
	Mild	-	-	-
	Moderate	1(0.6)	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.1.1.5

表 2.7.4.7-付録-19　有害事象の程度別発現頻度（133 試験）（71/97）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=159)	 0.5 mg (N=164)	 1 mg (N=149)
神経系障害（続き）				
神経圧迫	Overall	-	-	1(0.7)
	Mild	-	-	-
	Moderate	-	-	-
	Severe	-	-	1(0.7)
パーキンソン歩行	Overall	-	-	1(0.7)
	Mild	-	-	-
	Moderate	-	-	1(0.7)
	Severe	-	-	-
末梢性感覚ニューロパチー	Overall	1(0.6)	-	-
	Mild	-	-	-
	Moderate	1(0.6)	-	-
	Severe	-	-	-
ヘルペス後神経痛	Overall	-	1(0.6)	-
	Mild	-	1(0.6)	-
	Moderate	-	-	-
	Severe	-	-	-
外傷後頭痛	Overall	1(0.6)	-	-
	Mild	-	-	-
	Moderate	1(0.6)	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.1.1.5

表 2.7.4.7-付録-19　有害事象の程度別発現頻度（133 試験）（72/97）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=159)	 0.5 mg (N=164)	 1 mg (N=149)
神経系障害（続き）				
失神寸前の状態	Overall	1(0.6)	-	-
	Mild	-	-	-
	Moderate	-	-	-
	Severe	1(0.6)	-	-
橈骨神経麻痺	Overall	-	1(0.6)	-
	Mild	-	-	-
	Moderate	-	1(0.6)	-
	Severe	-	-	-
痙攣発作	Overall	-	1(0.6)	-
	Mild	-	-	-
	Moderate	-	1(0.6)	-
	Severe	-	-	-
副鼻腔炎に伴う頭痛	Overall	-	-	1(0.7)
	Mild	-	-	1(0.7)
	Moderate	-	-	-
	Severe	-	-	-
脊髄圧迫	Overall	-	-	1(0.7)
	Mild	-	-	-
	Moderate	-	-	-
	Severe	-	-	1(0.7)

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.1.1.5

表 2.7.4.7-付録-19　有害事象の程度別発現頻度（133 試験）（73/97）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=159)	 0.5 mg (N=164)	 1 mg (N=149)
神経系障害（続き）				
緊張性頭痛	Overall	-	1(0.6)	-
	Mild	-	1(0.6)	-
	Moderate	-	-	-
	Severe	-	-	-
中毒性脳症	Overall	1(0.6)	-	-
	Mild	-	-	-
	Moderate	-	-	-
	Severe	1(0.6)	-	-
精神障害	Overall	30(18.9)	34(20.7)	32(21.5)
	Mild	11(6.9)	14(8.5)	19(12.8)
	Moderate	18(11.3)	19(11.6)	13(8.7)
	Severe	1(0.6)	1(0.6)	-
不眠症	Overall	10(6.3)	12(7.3)	9(6.0)
	Mild	4(2.5)	3(1.8)	4(2.7)
	Moderate	6(3.8)	8(4.9)	5(3.4)
	Severe	-	1(0.6)	-
うつ病	Overall	8(5.0)	2(1.2)	6(4.0)
	Mild	3(1.9)	2(1.2)	2(1.3)
	Moderate	5(3.1)	-	4(2.7)
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]. Statistical Analysis Report (5.3.5.3-1) Table 2.1.1.5

表 2.7.4.7-付録-19　有害事象の程度別発現頻度（133 試験）（74/97）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=159)	 0.5 mg (N=164)	 1 mg (N=149)
精神障害（続き）				
幻覚	Overall	4(2.5)	6(3.7)	5(3.4)
	Mild	3(1.9)	3(1.8)	5(3.4)
	Moderate	1(0.6)	3(1.8)	-
	Severe	-	-	-
不安	Overall	5(3.1)	5(3.0)	2(1.3)
	Mild	-	2(1.2)	1(0.7)
	Moderate	5(3.1)	2(1.2)	1(0.7)
	Severe	-	1(0.6)	-
錯乱状態	Overall	1(0.6)	5(3.0)	2(1.3)
	Mild	-	2(1.2)	1(0.7)
	Moderate	1(0.6)	3(1.8)	1(0.7)
	Severe	-	-	-
異常な夢	Overall	1(0.6)	1(0.6)	4(2.7)
	Mild	1(0.6)	1(0.6)	3(2.0)
	Moderate	-	-	1(0.7)
	Severe	-	-	-
睡眠障害	Overall	2(1.3)	1(0.6)	3(2.0)
	Mild	2(1.3)	1(0.6)	2(1.3)
	Moderate	-	-	1(0.7)
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.1.1.5

表 2.7.4.7-付録-19　有害事象の程度別発現頻度（133 試験）（75/97）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=159)	 0.5 mg (N=164)	 1 mg (N=149)
精神障害（続き）				
抑うつ気分	Overall	2(1.3)	-	2(1.3)
	Mild	-	-	1(0.7)
	Moderate	2(1.3)	-	1(0.7)
	Severe	-	-	-
幻視	Overall	1(0.6)	2(1.2)	1(0.7)
	Mild	-	1(0.6)	-
	Moderate	-	1(0.6)	1(0.7)
	Severe	1(0.6)	-	-
悪夢	Overall	1(0.6)	1(0.6)	2(1.3)
	Mild	-	-	1(0.7)
	Moderate	1(0.6)	1(0.6)	1(0.7)
	Severe	-	-	-
神経過敏	Overall	1(0.6)	1(0.6)	-
	Mild	-	-	-
	Moderate	1(0.6)	1(0.6)	-
	Severe	-	-	-
パニック発作	Overall	2(1.3)	-	-
	Mild	-	-	-
	Moderate	2(1.3)	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.1.1.5

表 2.7.4.7-付録-19　有害事象の程度別発現頻度（133 試験）（76/97）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=159)	 0.5 mg (N=164)	 1 mg (N=149)
精神障害（続き）				
失見当識	Overall	-	1(0.6)	-
	Mild	-	-	-
	Moderate	-	1(0.6)	-
	Severe	-	-	-
欲求不満耐性低下	Overall	-	1(0.6)	-
	Mild	-	-	-
	Moderate	-	1(0.6)	-
	Severe	-	-	-
ギャンブル障害	Overall	-	1(0.6)	-
	Mild	-	-	-
	Moderate	-	1(0.6)	-
	Severe	-	-	-
幻聴	Overall	-	-	1(0.7)
	Mild	-	-	-
	Moderate	-	-	1(0.7)
	Severe	-	-	-
リビドー減退	Overall	-	-	1(0.7)
	Mild	-	-	1(0.7)
	Moderate	-	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]. Statistical Analysis Report (5.3.5.3-1) Table 2.1.1.5

表 2.7.4.7-付録-19　有害事象の程度別発現頻度（133 試験）（77/97）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=159)	 0.5 mg (N=164)	 1 mg (N=149)
精神障害（続き）				
妄想症	Overall	-	-	1(0.7)
	Mild	-	-	1(0.7)
	Moderate	-	-	-
	Severe	-	-	-
落ち着きのなさ	Overall	-	1(0.6)	-
	Mild	-	1(0.6)	-
	Moderate	-	-	-
	Severe	-	-	-
睡眠発作	Overall	1(0.6)	-	-
	Mild	1(0.6)	-	-
	Moderate	-	-	-
	Severe	-	-	-
社会逃避行動	Overall	-	-	1(0.7)
	Mild	-	-	-
	Moderate	-	-	1(0.7)
	Severe	-	-	-
腎および尿路障害	Overall	10(6.3)	10(6.1)	8(5.4)
	Mild	6(3.8)	6(3.7)	6(4.0)
	Moderate	2(1.3)	4(2.4)	2(1.3)
	Severe	2(1.3)	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.1.1.5

表 2.7.4.7-付録-19　有害事象の程度別発現頻度（133 試験）（78/97）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=159)	 0.5 mg (N=164)	 1 mg (N=149)
腎および尿路障害（続き）				
頻尿	Overall	1(0.6)	4(2.4)	-
	Mild	-	2(1.2)	-
	Moderate	1(0.6)	2(1.2)	-
	Severe	-	-	-
蛋白尿	Overall	1(0.6)	1(0.6)	2(1.3)
	Mild	1(0.6)	1(0.6)	2(1.3)
	Moderate	-	-	-
	Severe	-	-	-
排尿困難	Overall	1(0.6)	1(0.6)	1(0.7)
	Mild	-	1(0.6)	-
	Moderate	1(0.6)	-	1(0.7)
	Severe	-	-	-
血尿	Overall	-	2(1.2)	1(0.7)
	Mild	-	1(0.6)	-
	Moderate	-	1(0.6)	1(0.7)
	Severe	-	-	-
腎結石症	Overall	3(1.9)	-	-
	Mild	2(1.3)	-	-
	Moderate	-	-	-
	Severe	1(0.6)	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.1.1.5

表 2.7.4.7-付録-19　有害事象の程度別発現頻度（133 試験）（79/97）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=159)	 0.5 mg (N=164)	 1 mg (N=149)
腎および尿路障害（続き）				
尿失禁	Overall	1(0.6)	1(0.6)	1(0.7)
	Mild	1(0.6)	1(0.6)	1(0.7)
	Moderate	-	-	-
	Severe	-	-	-
夜間頻尿	Overall	-	-	2(1.3)
	Mild	-	-	2(1.3)
	Moderate	-	-	-
	Severe	-	-	-
急性腎障害	Overall	1(0.6)	-	-
	Mild	-	-	-
	Moderate	-	-	-
	Severe	1(0.6)	-	-
高窒素血症	Overall	-	1(0.6)	-
	Mild	-	-	-
	Moderate	-	1(0.6)	-
	Severe	-	-	-
膀胱痙縮	Overall	1(0.6)	-	-
	Mild	1(0.6)	-	-
	Moderate	-	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]. Statistical Analysis Report (5.3.5.3-1) Table 2.1.1.5

表 2.7.4.7-付録-19　有害事象の程度別発現頻度（133 試験）（80/97）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=159)	 0.5 mg (N=164)	 1 mg (N=149)
腎および尿路障害（続き）				
尿意切迫	Overall	-	-	1(0.7)
	Mild	-	-	1(0.7)
	Moderate	-	-	-
	Severe	-	-	-
多尿	Overall	1(0.6)	-	-
	Mild	1(0.6)	-	-
	Moderate	-	-	-
	Severe	-	-	-
腎嚢胞	Overall	-	1(0.6)	-
	Mild	-	-	-
	Moderate	-	1(0.6)	-
	Severe	-	-	-
腎不全	Overall	-	1(0.6)	-
	Mild	-	1(0.6)	-
	Moderate	-	-	-
	Severe	-	-	-
排尿躊躇	Overall	-	1(0.6)	-
	Mild	-	1(0.6)	-
	Moderate	-	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]　Statistical Analysis Report (5.3.5.3-1) Table 2.1.1.5

表 2.7.4.7-付録-19　有害事象の程度別発現頻度（133 試験）（81/97）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=159)	 0.5 mg (N=164)	 1 mg (N=149)
腎および尿路障害（続き）				
尿閉	Overall	1(0.6)	-	-
	Mild	1(0.6)	-	-
	Moderate	-	-	-
	Severe	-	-	-
生殖系および乳房障害	Overall	4(2.5)	4(2.4)	4(2.7)
	Mild	1(0.6)	4(2.4)	3(2.0)
	Moderate	3(1.9)	-	1(0.7)
	Severe	-	-	-
勃起不全	Overall	2(1.3)	1(0.6)	-
	Mild	-	1(0.6)	-
	Moderate	2(1.3)	-	-
	Severe	-	-	-
前立腺炎	Overall	1(0.6)	1(0.6)	1(0.7)
	Mild	-	1(0.6)	-
	Moderate	1(0.6)	-	1(0.7)
	Severe	-	-	-
良性前立腺肥大症	Overall	-	1(0.6)	-
	Mild	-	1(0.6)	-
	Moderate	-	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]. Statistical Analysis Report (5.3.5.3-1) Table 2.1.1.5

表 2.7.4.7-付録-19　有害事象の程度別発現頻度（133 試験）（82/97）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=159)	 0.5 mg (N=164)	 1 mg (N=149)
生殖系および乳房障害（続き）				
月経困難症	Overall	-	-	1(0.7)
	Mild	-	-	1(0.7)
	Moderate	-	-	-
	Severe	-	-	-
月経過多	Overall	-	1(0.6)	-
	Mild	-	1(0.6)	-
	Moderate	-	-	-
	Severe	-	-	-
前立腺腫大	Overall	1(0.6)	-	-
	Mild	1(0.6)	-	-
	Moderate	-	-	-
	Severe	-	-	-
遊走精巣	Overall	-	-	1(0.7)
	Mild	-	-	1(0.7)
	Moderate	-	-	-
	Severe	-	-	-
腟出血	Overall	-	-	1(0.7)
	Mild	-	-	1(0.7)
	Moderate	-	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.1.1.5

表 2.7.4.7-付録-19　有害事象の程度別発現頻度（133 試験）（83/97）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=159)	 0.5 mg (N=164)	 1 mg (N=149)
生殖系および乳房障害（続き）				
外陰腟そう痒症	Overall	-	1(0.6)	-
	Mild	-	1(0.6)	-
	Moderate	-	-	-
	Severe	-	-	-
呼吸器、胸郭および縦隔障害	Overall	19(11.9)	22(13.4)	20(13.4)
	Mild	16(10.1)	9(5.5)	14(9.4)
	Moderate	1(0.6)	10(6.1)	5(3.4)
	Severe	2(1.3)	3(1.8)	1(0.7)
呼吸困難	Overall	3(1.9)	9(5.5)	4(2.7)
	Mild	2(1.3)	4(2.4)	3(2.0)
	Moderate	-	3(1.8)	1(0.7)
	Severe	1(0.6)	2(1.2)	-
口腔咽頭痛	Overall	5(3.1)	2(1.2)	3(2.0)
	Mild	4(2.5)	2(1.2)	3(2.0)
	Moderate	1(0.6)	-	-
	Severe	-	-	-
咳嗽	Overall	4(2.5)	1(0.6)	2(1.3)
	Mild	4(2.5)	1(0.6)	1(0.7)
	Moderate	-	-	1(0.7)
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.1.1.5

表 2.7.4.7-付録-19　有害事象の程度別発現頻度（133 試験）（84/97）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=159)	 0.5 mg (N=164)	 1 mg (N=149)
呼吸器、胸郭および縦隔障害（続き）				
鼻出血	Overall	-	3(1.8)	2(1.3)
	Mild	-	2(1.2)	1(0.7)
	Moderate	-	1(0.6)	1(0.7)
	Severe	-	-	-
鼻閉	Overall	2(1.3)	2(1.2)	1(0.7)
	Mild	2(1.3)	1(0.6)	1(0.7)
	Moderate	-	1(0.6)	-
	Severe	-	-	-
副鼻腔うっ血	Overall	1(0.6)	2(1.2)	2(1.3)
	Mild	1(0.6)	2(1.2)	1(0.7)
	Moderate	-	-	1(0.7)
	Severe	-	-	-
気道うっ血	Overall	3(1.9)	-	-
	Mild	3(1.9)	-	-
	Moderate	-	-	-
	Severe	-	-	-
鼻漏	Overall	1(0.6)	1(0.6)	1(0.7)
	Mild	-	1(0.6)	1(0.7)
	Moderate	1(0.6)	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.1.1.5

表 2.7.4.7-付録-19　有害事象の程度別発現頻度（133 試験）（85/97）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=159)	 0.5 mg (N=164)	 1 mg (N=149)
呼吸器、胸郭および縦隔障害（続き）				
肺塞栓症	Overall	-	1(0.6)	1(0.7)
	Mild	-	-	-
	Moderate	-	1(0.6)	-
	Severe	-	-	1(0.7)
上気道咳症候群	Overall	-	2(1.2)	-
	Mild	-	-	-
	Moderate	-	2(1.2)	-
	Severe	-	-	-
アレルギー性副鼻腔炎	Overall	-	-	1(0.7)
	Mild	-	-	1(0.7)
	Moderate	-	-	-
	Severe	-	-	-
喘息	Overall	-	-	1(0.7)
	Mild	-	-	-
	Moderate	-	-	1(0.7)
	Severe	-	-	-
気管支痙攣	Overall	-	1(0.6)	-
	Mild	-	-	-
	Moderate	-	1(0.6)	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.1.1.5

表 2.7.4.7-付録-19　有害事象の程度別発現頻度（133 試験）（86/97）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=159)	 0.5 mg (N=164)	 1 mg (N=149)
呼吸器、胸郭および縦隔障害（続き）				
鼻乾燥	Overall	1(0.6)	-	-
	Mild	1(0.6)	-	-
	Moderate	-	-	-
	Severe	-	-	-
夜間呼吸困難	Overall	-	-	1(0.7)
	Mild	-	-	1(0.7)
	Moderate	-	-	-
	Severe	-	-	-
副鼻腔分泌過多	Overall	1(0.6)	-	-
	Mild	1(0.6)	-	-
	Moderate	-	-	-
	Severe	-	-	-
胸水	Overall	-	1(0.6)	-
	Mild	-	-	-
	Moderate	-	1(0.6)	-
	Severe	-	-	-
胸膜炎	Overall	-	-	1(0.7)
	Mild	-	-	1(0.7)
	Moderate	-	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.1.1.5

表 2.7.4.7-付録-19　有害事象の程度別発現頻度（133 試験）（87/97）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=159)	 0.5 mg (N=164)	 1 mg (N=149)
呼吸器、胸郭および縦隔障害（続き）				
湿性咳嗽	Overall	-	-	1(0.7)
	Mild	-	-	-
	Moderate	-	-	1(0.7)
	Severe	-	-	-
肺水腫	Overall	1(0.6)	-	-
	Mild	-	-	-
	Moderate	-	-	-
	Severe	1(0.6)	-	-
肺血栓症	Overall	-	1(0.6)	-
	Mild	-	-	-
	Moderate	-	-	-
	Severe	-	1(0.6)	-
鼻痛	Overall	-	-	1(0.7)
	Mild	-	-	1(0.7)
	Moderate	-	-	-
	Severe	-	-	-
くしゃみ	Overall	1(0.6)	-	-
	Mild	1(0.6)	-	-
	Moderate	-	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]　Statistical Analysis Report (5.3.5.3-1) Table 2.1.1.5

表 2.7.4.7-付録-19　有害事象の程度別発現頻度（133 試験）（88/97）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=159)	 0.5 mg (N=164)	 1 mg (N=149)
呼吸器、胸郭および縦隔障害（続き）				
咽喉刺激感	Overall	-	-	1(0.7)
	Mild	-	-	1(0.7)
	Moderate	-	-	-
	Severe	-	-	-
上気道うっ血	Overall	-	1(0.6)	-
	Mild	-	-	-
	Moderate	-	1(0.6)	-
	Severe	-	-	-
皮膚および皮下組織障害	Overall	22(13.8)	19(11.6)	24(16.1)
	Mild	15(9.4)	13(7.9)	23(15.4)
	Moderate	7(4.4)	4(2.4)	-
	Severe	-	2(1.2)	1(0.7)
多汗症	Overall	2(1.3)	4(2.4)	5(3.4)
	Mild	2(1.3)	2(1.2)	4(2.7)
	Moderate	-	2(1.2)	-
	Severe	-	-	1(0.7)
発疹	Overall	-	3(1.8)	4(2.7)
	Mild	-	3(1.8)	4(2.7)
	Moderate	-	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]. Statistical Analysis Report (5.3.5.3-1) Table 2.1.1.5

表 2.7.4.7-付録-19　有害事象の程度別発現頻度（133 試験）（89/97）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=159)	 0.5 mg (N=164)	 1 mg (N=149)
皮膚および皮下組織障害（続き）				
紅斑	Overall	2(1.3)	2(1.2)	2(1.3)
	Mild	1(0.6)	1(0.6)	2(1.3)
	Moderate	1(0.6)	1(0.6)	-
	Severe	-	-	-
斑状出血	Overall	2(1.3)	-	2(1.3)
	Mild	1(0.6)	-	2(1.3)
	Moderate	1(0.6)	-	-
	Severe	-	-	-
湿疹	Overall	3(1.9)	1(0.6)	-
	Mild	1(0.6)	1(0.6)	-
	Moderate	2(1.3)	-	-
	Severe	-	-	-
そう痒症	Overall	1(0.6)	1(0.6)	2(1.3)
	Mild	1(0.6)	1(0.6)	2(1.3)
	Moderate	-	-	-
	Severe	-	-	-
光線角化症	Overall	1(0.6)	1(0.6)	1(0.7)
	Mild	1(0.6)	1(0.6)	1(0.7)
	Moderate	-	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]　Statistical Analysis Report (5.3.5.3-1) Table 2.1.1.5

表 2.7.4.7-付録-19　有害事象の程度別発現頻度（133 試験）（90/97）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=159)	 0.5 mg (N=164)	 1 mg (N=149)
皮膚および皮下組織障害（続き）				
接触性皮膚炎	Overall	2(1.3)	1(0.6)	-
	Mild	1(0.6)	-	-
	Moderate	1(0.6)	-	-
	Severe	-	1(0.6)	-
皮膚乾燥	Overall	1(0.6)	1(0.6)	1(0.7)
	Mild	1(0.6)	1(0.6)	1(0.7)
	Moderate	-	-	-
	Severe	-	-	-
皮膚剥脱	Overall	1(0.6)	-	2(1.3)
	Mild	1(0.6)	-	2(1.3)
	Moderate	-	-	-
	Severe	-	-	-
丘疹	Overall	1(0.6)	-	1(0.7)
	Mild	1(0.6)	-	1(0.7)
	Moderate	-	-	-
	Severe	-	-	-
丘疹性皮疹	Overall	-	1(0.6)	1(0.7)
	Mild	-	-	1(0.7)
	Moderate	-	-	-
	Severe	-	1(0.6)	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.1.1.5

表 2.7.4.7-付録-19　有害事象の程度別発現頻度（133 試験）（91/97）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=159)	 0.5 mg (N=164)	 1 mg (N=149)
皮膚および皮下組織障害（続き）				
痂皮	Overall	1(0.6)	-	1(0.7)
	Mild	1(0.6)	-	1(0.7)
	Moderate	-	-	-
	Severe	-	-	-
日光黒子	Overall	1(0.6)	1(0.6)	-
	Mild	1(0.6)	1(0.6)	-
	Moderate	-	-	-
	Severe	-	-	-
蕁麻疹	Overall	1(0.6)	1(0.6)	-
	Mild	-	-	-
	Moderate	1(0.6)	1(0.6)	-
	Severe	-	-	-
ざ瘡	Overall	-	1(0.6)	-
	Mild	-	1(0.6)	-
	Moderate	-	-	-
	Severe	-	-	-
褥瘡性潰瘍	Overall	-	-	1(0.7)
	Mild	-	-	1(0.7)
	Moderate	-	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.1.1.5

表 2.7.4.7-付録-19　有害事象の程度別発現頻度（133 試験）（92/97）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=159)	 0.5 mg (N=164)	 1 mg (N=149)
皮膚および皮下組織障害（続き）				
貨幣状湿疹	Overall	1(0.6)	-	-
	Mild	1(0.6)	-	-
	Moderate	-	-	-
	Severe	-	-	-
過角化	Overall	1(0.6)	-	-
	Mild	1(0.6)	-	-
	Moderate	-	-	-
	Severe	-	-	-
過敏性血管炎	Overall	-	1(0.6)	-
	Mild	-	-	-
	Moderate	-	1(0.6)	-
	Severe	-	-	-
黒子	Overall	-	-	1(0.7)
	Mild	-	-	1(0.7)
	Moderate	-	-	-
	Severe	-	-	-
苔癬様角化症	Overall	-	1(0.6)	-
	Mild	-	1(0.6)	-
	Moderate	-	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.1.1.5

表 2.7.4.7-付録-19　有害事象の程度別発現頻度（133 試験）（93/97）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=159)	 0.5 mg (N=164)	 1 mg (N=149)
皮膚および皮下組織障害（続き）				
神経皮膚炎	Overall	-	1(0.6)	-
	Mild	-	1(0.6)	-
	Moderate	-	-	-
	Severe	-	-	-
爪破損	Overall	-	-	1(0.7)
	Mild	-	-	1(0.7)
	Moderate	-	-	-
	Severe	-	-	-
光線過敏性反応	Overall	-	1(0.6)	-
	Mild	-	1(0.6)	-
	Moderate	-	-	-
	Severe	-	-	-
乾癬	Overall	-	-	1(0.7)
	Mild	-	-	1(0.7)
	Moderate	-	-	-
	Severe	-	-	-
紅斑性皮疹	Overall	1(0.6)	-	-
	Mild	1(0.6)	-	-
	Moderate	-	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.1.1.5

表 2.7.4.7-付録-19　有害事象の程度別発現頻度（133 試験）（94/97）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=159)	 0.5 mg (N=164)	 1 mg (N=149)
皮膚および皮下組織障害（続き）				
斑状皮疹	Overall	1(0.6)	-	-
	Mild	-	-	-
	Moderate	1(0.6)	-	-
	Severe	-	-	-
酒さ	Overall	1(0.6)	-	-
	Mild	1(0.6)	-	-
	Moderate	-	-	-
	Severe	-	-	-
脂漏性皮膚炎	Overall	1(0.6)	-	-
	Mild	1(0.6)	-	-
	Moderate	-	-	-
	Severe	-	-	-
皮膚変色	Overall	-	1(0.6)	-
	Mild	-	1(0.6)	-
	Moderate	-	-	-
	Severe	-	-	-
皮膚潰瘍	Overall	1(0.6)	-	-
	Mild	-	-	-
	Moderate	1(0.6)	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.1.1.5

表 2.7.4.7-付録-19　有害事象の程度別発現頻度（133 試験）（95/97）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=159)	 0.5 mg (N=164)	 1 mg (N=149)
外科および内科処置	Overall	2(1.3)	-	-
	Mild	1(0.6)	-	-
	Moderate	1(0.6)	-	-
	Severe	-	-	-
バニオン手術	Overall	1(0.6)	-	-
	Mild	-	-	-
	Moderate	1(0.6)	-	-
	Severe	-	-	-
副鼻腔手術	Overall	1(0.6)	-	-
	Mild	1(0.6)	-	-
	Moderate	-	-	-
	Severe	-	-	-
腱形成	Overall	1(0.6)	-	-
	Mild	-	-	-
	Moderate	1(0.6)	-	-
	Severe	-	-	-
血管障害	Overall	9(5.7)	15(9.1)	18(12.1)
	Mild	4(2.5)	9(5.5)	10(6.7)
	Moderate	4(2.5)	6(3.7)	6(4.0)
	Severe	1(0.6)	-	2(1.3)
起立性低血圧	Overall	3(1.9)	7(4.3)	11(7.4)
	Mild	1(0.6)	4(2.4)	6(4.0)
	Moderate	2(1.3)	3(1.8)	4(2.7)
	Severe	-	-	1(0.7)

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.1.1.5

表 2.7.4.7-付録-19　有害事象の程度別発現頻度（133 試験）（96/97）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=159)	 0.5 mg (N=164)	 1 mg (N=149)
血管障害（続き）				
高血圧	Overall	4(2.5)	4(2.4)	1(0.7)
	Mild	3(1.9)	2(1.2)	1(0.7)
	Moderate	-	2(1.2)	-
	Severe	1(0.6)	-	-
低血圧	Overall	1(0.6)	3(1.8)	1(0.7)
	Mild	-	2(1.2)	1(0.7)
	Moderate	1(0.6)	1(0.6)	-
	Severe	-	-	-
潮紅	Overall	1(0.6)	-	1(0.7)
	Mild	1(0.6)	-	-
	Moderate	-	-	1(0.7)
	Severe	-	-	-
血腫	Overall	-	1(0.6)	1(0.7)
	Mild	-	1(0.6)	-
	Moderate	-	-	1(0.7)
	Severe	-	-	-
ほてり	Overall	-	-	1(0.7)
	Mild	-	-	1(0.7)
	Moderate	-	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.1.1.5

表 2.7.4.7-付録-19　有害事象の程度別発現頻度（133 試験）（97/97）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=159)	 0.5 mg (N=164)	 1 mg (N=149)
血管障害（続き）				
間欠性跛行	Overall	-	-	1(0.7)
	Mild	-	-	1(0.7)
	Moderate	-	-	-
	Severe	-	-	-
収縮期高血圧	Overall	1(0.6)	-	-
	Mild	-	-	-
	Moderate	1(0.6)	-	-
	Severe	-	-	-
血栓症	Overall	-	-	1(0.7)
	Mild	-	-	-
	Moderate	-	-	-
	Severe	-	-	1(0.7)
静脈瘤	Overall	1(0.6)	-	-
	Mild	-	-	-
	Moderate	1(0.6)	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]. Statistical Analysis Report (5.3.5.3-1) Table 2.1.1.5

表 2.7.4.7-付録-20　有害事象の程度別発現頻度（122 試験）（1/60）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=229)	 1 mg (N=231)	 Entacapone (N=227)
Subjects with Any TEAEs	Overall	108(47.2)	109(47.2)	126(55.5)
	Mild	44(19.2)	49(21.2)	65(28.6)
	Moderate	55(24.0)	50(21.6)	46(20.3)
	Severe	9(3.9)	10(4.3)	15(6.6)
血液およびリンパ系障害	Overall	-	4(1.7)	-
	Mild	-	2(0.9)	-
	Moderate	-	1(0.4)	-
	Severe	-	1(0.4)	-
貧血	Overall	-	1(0.4)	-
	Mild	-	-	-
	Moderate	-	-	-
	Severe	-	1(0.4)	-
免疫性血小板減少性紫斑病	Overall	-	1(0.4)	-
	Mild	-	1(0.4)	-
	Moderate	-	-	-
	Severe	-	-	-
白血球減少症	Overall	-	1(0.4)	-
	Mild	-	1(0.4)	-
	Moderate	-	-	-
	Severe	-	-	-
好中球増加症	Overall	-	1(0.4)	-
	Mild	-	-	-
	Moderate	-	1(0.4)	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.2.1.5

表 2.7.4.7-付録-20　有害事象の程度別発現頻度（122 試験）（2/60）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=229)	 1 mg (N=231)	 Entacapone (N=227)
心臓障害	Overall	8(3.5)	14(6.1)	2(0.9)
	Mild	4(1.7)	9(3.9)	1(0.4)
	Moderate	4(1.7)	3(1.3)	1(0.4)
	Severe	-	2(0.9)	-
心房細動	Overall	2(0.9)	1(0.4)	1(0.4)
	Mild	-	-	1(0.4)
	Moderate	2(0.9)	-	-
	Severe	-	1(0.4)	-
第一度房室ブロック	Overall	-	3(1.3)	-
	Mild	-	2(0.9)	-
	Moderate	-	1(0.4)	-
	Severe	-	-	-
心不全	Overall	2(0.9)	1(0.4)	-
	Mild	2(0.9)	-	-
	Moderate	-	-	-
	Severe	-	1(0.4)	-
狭心症	Overall	-	2(0.9)	-
	Mild	-	1(0.4)	-
	Moderate	-	1(0.4)	-
	Severe	-	-	-
徐脈	Overall	-	2(0.9)	-
	Mild	-	1(0.4)	-
	Moderate	-	1(0.4)	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.2.1.5

表 2.7.4.7-付録-20　有害事象の程度別発現頻度（122 試験）（3/60）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=229)	 1 mg (N=231)	 Entacapone (N=227)
心臓障害（続き）				
左脚ブロック	Overall	-	2(0.9)	-
	Mild	-	2(0.9)	-
	Moderate	-	-	-
	Severe	-	-	-
慢性心不全	Overall	2(0.9)	-	-
	Mild	-	-	-
	Moderate	2(0.9)	-	-
	Severe	-	-	-
心筋虚血	Overall	1(0.4)	1(0.4)	-
	Mild	1(0.4)	-	-
	Moderate	-	1(0.4)	-
	Severe	-	-	-
上室性不整脈	Overall	1(0.4)	-	-
	Mild	-	-	-
	Moderate	1(0.4)	-	-
	Severe	-	-	-
完全房室ブロック	Overall	-	1(0.4)	-
	Mild	-	-	-
	Moderate	-	-	-
	Severe	-	1(0.4)	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.2.1.5

表 2.7.4.7-付録-20　有害事象の程度別発現頻度（122 試験）（4/60）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=229)	 1 mg (N=231)	 Entacapone (N=227)
心臓障害（続き）				
第二度房室ブロック	Overall	-	1(0.4)	-
	Mild	-	-	-
	Moderate	-	1(0.4)	-
	Severe	-	-	-
右脚ブロック	Overall	1(0.4)	-	-
	Mild	1(0.4)	-	-
	Moderate	-	-	-
	Severe	-	-	-
僧帽弁疾患	Overall	-	-	1(0.4)
	Mild	-	-	-
	Moderate	-	-	1(0.4)
	Severe	-	-	-
無症候性心筋梗塞	Overall	-	1(0.4)	-
	Mild	-	1(0.4)	-
	Moderate	-	-	-
	Severe	-	-	-
洞性徐脈	Overall	-	-	1(0.4)
	Mild	-	-	1(0.4)
	Moderate	-	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.2.1.5

表 2.7.4.7-付録-20　有害事象の程度別発現頻度（122 試験）（5/60）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=229)	 1 mg (N=231)	 Entacapone (N=227)
心臓障害（続き）				
洞結節機能不全	Overall	-	1(0.4)	-
	Mild	-	-	-
	Moderate	-	-	-
	Severe	-	1(0.4)	-
三尖弁疾患	Overall	-	-	1(0.4)
	Mild	-	-	-
	Moderate	-	-	1(0.4)
	Severe	-	-	-
心室性不整脈	Overall	-	1(0.4)	-
	Mild	-	1(0.4)	-
	Moderate	-	-	-
	Severe	-	-	-
心室性期外収縮	Overall	-	1(0.4)	-
	Mild	-	1(0.4)	-
	Moderate	-	-	-
	Severe	-	-	-
耳および迷路障害	Overall	3(1.3)	2(0.9)	5(2.2)
	Mild	1(0.4)	-	3(1.3)
	Moderate	2(0.9)	1(0.4)	2(0.9)
	Severe	-	1(0.4)	-

有害事象名：MedDRA/J ver[redacted]. Statistical Analysis Report (5.3.5.3-1) Table 2.2.1.5

表 2.7.4.7-付録-20　有害事象の程度別発現頻度（122 試験）（6/60）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=229)	 1 mg (N=231)	 Entacapone (N=227)
耳および迷路障害（続き）				
回転性めまい	Overall	3(1.3)	1(0.4)	3(1.3)
	Mild	1(0.4)	-	1(0.4)
	Moderate	2(0.9)	-	2(0.9)
	Severe	-	1(0.4)	-
乗物酔い	Overall	-	1(0.4)	2(0.9)
	Mild	-	-	2(0.9)
	Moderate	-	1(0.4)	-
	Severe	-	-	-
耳鳴	Overall	-	-	1(0.4)
	Mild	-	-	1(0.4)
	Moderate	-	-	-
	Severe	-	-	-
眼障害	Overall	2(0.9)	3(1.3)	4(1.8)
	Mild	-	-	3(1.3)
	Moderate	2(0.9)	2(0.9)	1(0.4)
	Severe	-	1(0.4)	-
霧視	Overall	1(0.4)	1(0.4)	-
	Mild	-	-	-
	Moderate	1(0.4)	1(0.4)	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.2.1.5

表 2.7.4.7-付録-20　有害事象の程度別発現頻度（122 試験）（7/60）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=229)	 1 mg (N=231)	 Entacapone (N=227)
眼障害（続き）				
視力障害	Overall	-	-	2(0.9)
	Mild	-	-	1(0.4)
	Moderate	-	-	1(0.4)
	Severe	-	-	-
一過性黒内障	Overall	-	-	1(0.4)
	Mild	-	-	1(0.4)
	Moderate	-	-	-
	Severe	-	-	-
一過性失明	Overall	-	1(0.4)	-
	Mild	-	-	-
	Moderate	-	-	-
	Severe	-	1(0.4)	-
複視	Overall	-	-	1(0.4)
	Mild	-	-	1(0.4)
	Moderate	-	-	-
	Severe	-	-	-
眼痛	Overall	1(0.4)	-	-
	Mild	-	-	-
	Moderate	1(0.4)	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.2.1.5

表 2.7.4.7-付録-20　有害事象の程度別発現頻度（122 試験）（8/60）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=229)	 1 mg (N=231)	 Entacapone (N=227)
眼障害（続き）				
注視麻痺	Overall	-	1(0.4)	-
	Mild	-	-	-
	Moderate	-	1(0.4)	-
	Severe	-	-	-
胃腸障害	Overall	22(9.6)	26(11.3)	34(15.0)
	Mild	14(6.1)	13(5.6)	23(10.1)
	Moderate	8(3.5)	12(5.2)	7(3.1)
	Severe	-	1(0.4)	4(1.8)
悪心	Overall	10(4.4)	8(3.5)	13(5.7)
	Mild	7(3.1)	6(2.6)	11(4.8)
	Moderate	3(1.3)	2(0.9)	1(0.4)
	Severe	-	-	1(0.4)
下痢	Overall	8(3.5)	3(1.3)	9(4.0)
	Mild	4(1.7)	-	6(2.6)
	Moderate	4(1.7)	3(1.3)	1(0.4)
	Severe	-	-	2(0.9)
上腹部痛	Overall	1(0.4)	5(2.2)	3(1.3)
	Mild	1(0.4)	3(1.3)	2(0.9)
	Moderate	-	2(0.9)	1(0.4)
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.2.1.5

表 2.7.4.7-付録-20　有害事象の程度別発現頻度（122 試験）（9/60）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=229)	 1 mg (N=231)	 Entacapone (N=227)
胃腸障害（続き）				
腹痛	Overall	2(0.9)	2(0.9)	3(1.3)
	Mild	1(0.4)	-	2(0.9)
	Moderate	1(0.4)	2(0.9)	1(0.4)
	Severe	-	-	-
便秘	Overall	-	3(1.3)	4(1.8)
	Mild	-	1(0.4)	2(0.9)
	Moderate	-	2(0.9)	2(0.9)
	Severe	-	-	-
口内乾燥	Overall	2(0.9)	4(1.7)	1(0.4)
	Mild	2(0.9)	3(1.3)	1(0.4)
	Moderate	-	1(0.4)	-
	Severe	-	-	-
嘔吐	Overall	2(0.9)	3(1.3)	2(0.9)
	Mild	1(0.4)	1(0.4)	1(0.4)
	Moderate	1(0.4)	2(0.9)	-
	Severe	-	-	1(0.4)
消化不良	Overall	3(1.3)	1(0.4)	1(0.4)
	Mild	3(1.3)	1(0.4)	1(0.4)
	Moderate	-	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.2.1.5

表 2.7.4.7-付録-20　有害事象の程度別発現頻度（122 試験）（10/60）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=229)	 1 mg (N=231)	 Entacapone (N=227)
胃腸障害（続き）				
鼠径ヘルニア	Overall	1(0.4)	1(0.4)	1(0.4)
	Mild	1(0.4)	1(0.4)	-
	Moderate	-	-	1(0.4)
	Severe	-	-	-
胃障害	Overall	-	1(0.4)	1(0.4)
	Mild	-	-	1(0.4)
	Moderate	-	1(0.4)	-
	Severe	-	-	-
胃食道逆流性疾患	Overall	-	2(0.9)	-
	Mild	-	1(0.4)	-
	Moderate	-	1(0.4)	-
	Severe	-	-	-
胃酸過多	Overall	-	1(0.4)	1(0.4)
	Mild	-	-	1(0.4)
	Moderate	-	1(0.4)	-
	Severe	-	-	-
腹部不快感	Overall	-	1(0.4)	-
	Mild	-	1(0.4)	-
	Moderate	-	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.2.1.5

表 2.7.4.7-付録-20　有害事象の程度別発現頻度（122 試験）（11/60）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=229)	 1 mg (N=231)	 Entacapone (N=227)
胃腸障害（続き）				
腹部ヘルニア	Overall	-	1(0.4)	-
	Mild	-	-	-
	Moderate	-	1(0.4)	-
	Severe	-	-	-
アフタ性潰瘍	Overall	1(0.4)	-	-
	Mild	-	-	-
	Moderate	1(0.4)	-	-
	Severe	-	-	-
慢性胃炎	Overall	-	1(0.4)	-
	Mild	-	1(0.4)	-
	Moderate	-	-	-
	Severe	-	-	-
嚥下障害	Overall	-	-	1(0.4)
	Mild	-	-	-
	Moderate	-	-	1(0.4)
	Severe	-	-	-
鼓腸	Overall	-	1(0.4)	-
	Mild	-	-	-
	Moderate	-	1(0.4)	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]. Statistical Analysis Report (5.3.5.3-1) Table 2.2.1.5

表 2.7.4.7-付録-20　有害事象の程度別発現頻度（122 試験）（12/60）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=229)	 1 mg (N=231)	 Entacapone (N=227)
胃腸障害（続き）				
胃出血	Overall	-	1(0.4)	-
	Mild	-	-	-
	Moderate	-	1(0.4)	-
	Severe	-	-	-
胃腸出血	Overall	-	-	1(0.4)
	Mild	-	-	-
	Moderate	-	-	1(0.4)
	Severe	-	-	-
消化管運動障害	Overall	-	1(0.4)	-
	Mild	-	1(0.4)	-
	Moderate	-	-	-
	Severe	-	-	-
巨大結腸	Overall	-	1(0.4)	-
	Mild	-	-	-
	Moderate	-	-	-
	Severe	-	1(0.4)	-
口腔内潰瘍形成	Overall	-	1(0.4)	-
	Mild	-	1(0.4)	-
	Moderate	-	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.2.1.5

表 2.7.4.7-付録-20　有害事象の程度別発現頻度（122 試験）（13/60）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=229)	 1 mg (N=231)	 Entacapone (N=227)
胃腸障害（続き）				
膵嚢胞	Overall	1(0.4)	-	-
	Mild	1(0.4)	-	-
	Moderate	-	-	-
	Severe	-	-	-
流涎過多	Overall	-	-	1(0.4)
	Mild	-	-	1(0.4)
	Moderate	-	-	-
	Severe	-	-	-
腸の軸捻転	Overall	-	1(0.4)	-
	Mild	-	-	-
	Moderate	-	-	-
	Severe	-	1(0.4)	-
一般・全身障害および投与部位の状態	Overall	12(5.2)	8(3.5)	10(4.4)
	Mild	6(2.6)	5(2.2)	5(2.2)
	Moderate	5(2.2)	3(1.3)	4(1.8)
	Severe	1(0.4)	-	1(0.4)
無力症	Overall	2(0.9)	1(0.4)	4(1.8)
	Mild	1(0.4)	1(0.4)	3(1.3)
	Moderate	1(0.4)	-	1(0.4)
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.2.1.5

表 2.7.4.7-付録-20　有害事象の程度別発現頻度（122 試験）（14/60）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=229)	 1 mg (N=231)	 Entacapone (N=227)
一般・全身障害および投与部位の状態（続き）				
末梢性浮腫	Overall	3(1.3)	3(1.3)	1(0.4)
	Mild	2(0.9)	1(0.4)	-
	Moderate	1(0.4)	2(0.9)	1(0.4)
	Severe	-	-	-
発熱	Overall	3(1.3)	2(0.9)	-
	Mild	1(0.4)	2(0.9)	-
	Moderate	2(0.9)	-	-
	Severe	-	-	-
疲労	Overall	2(0.9)	1(0.4)	1(0.4)
	Mild	1(0.4)	1(0.4)	1(0.4)
	Moderate	1(0.4)	-	-
	Severe	-	-	-
胸痛	Overall	1(0.4)	-	2(0.9)
	Mild	-	-	-
	Moderate	1(0.4)	-	2(0.9)
	Severe	-	-	-
末梢腫脹	Overall	1(0.4)	1(0.4)	1(0.4)
	Mild	1(0.4)	-	1(0.4)
	Moderate	-	1(0.4)	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]. Statistical Analysis Report (5.3.5.3-1) Table 2.2.1.5

表 2.7.4.7-付録-20　有害事象の程度別発現頻度（122 試験）（15/60）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=229)	 1 mg (N=231)	 Entacapone (N=227)
一般・全身障害および投与部位の状態（続き）				
死亡	Overall	-	-	1(0.4)
	Mild	-	-	-
	Moderate	-	-	-
	Severe	-	-	1(0.4)
顔面浮腫	Overall	1(0.4)	-	-
	Mild	1(0.4)	-	-
	Moderate	-	-	-
	Severe	-	-	-
異常感	Overall	1(0.4)	-	-
	Mild	1(0.4)	-	-
	Moderate	-	-	-
	Severe	-	-	-
全身健康状態低下	Overall	-	1(0.4)	-
	Mild	-	1(0.4)	-
	Moderate	-	-	-
	Severe	-	-	-
浮腫	Overall	-	-	1(0.4)
	Mild	-	-	1(0.4)
	Moderate	-	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.2.1.5

表 2.7.4.7-付録-20　有害事象の程度別発現頻度（122 試験）（16/60）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=229)	 1 mg (N=231)	 Entacapone (N=227)
一般・全身障害および投与部位の状態（続き）				
突然死	Overall	1(0.4)	-	-
	Mild	-	-	-
	Moderate	-	-	-
	Severe	1(0.4)	-	-
肝胆道系障害	Overall	1(0.4)	-	2(0.9)
	Mild	1(0.4)	-	1(0.4)
	Moderate	-	-	1(0.4)
	Severe	-	-	-
胆石症	Overall	1(0.4)	-	1(0.4)
	Mild	1(0.4)	-	-
	Moderate	-	-	1(0.4)
	Severe	-	-	-
脂肪肝	Overall	-	-	1(0.4)
	Mild	-	-	1(0.4)
	Moderate	-	-	-
	Severe	-	-	-
感染症および寄生虫症	Overall	16(7.0)	17(7.4)	25(11.0)
	Mild	9(3.9)	11(4.8)	16(7.0)
	Moderate	6(2.6)	4(1.7)	7(3.1)
	Severe	1(0.4)	2(0.9)	2(0.9)

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.2.1.5

表 2.7.4.7-付録-20　有害事象の程度別発現頻度（122 試験）（17/60）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=229)	 1 mg (N=231)	 Entacapone (N=227)
感染症および寄生虫症（続き）				
尿路感染	Overall	3(1.3)	2(0.9)	9(4.0)
	Mild	2(0.9)	2(0.9)	7(3.1)
	Moderate	1(0.4)	-	1(0.4)
	Severe	-	-	1(0.4)
気管支炎	Overall	2(0.9)	1(0.4)	3(1.3)
	Mild	-	1(0.4)	-
	Moderate	2(0.9)	-	3(1.3)
	Severe	-	-	-
インフルエンザ	Overall	2(0.9)	2(0.9)	2(0.9)
	Mild	2(0.9)	2(0.9)	2(0.9)
	Moderate	-	-	-
	Severe	-	-	-
鼻咽頭炎	Overall	1(0.4)	3(1.3)	1(0.4)
	Mild	1(0.4)	3(1.3)	1(0.4)
	Moderate	-	-	-
	Severe	-	-	-
下気道感染	Overall	2(0.9)	2(0.9)	-
	Mild	2(0.9)	1(0.4)	-
	Moderate	-	1(0.4)	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.2.1.5

表 2.7.4.7-付録-20　有害事象の程度別発現頻度（122 試験）（18/60）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=229)	 1 mg (N=231)	 Entacapone (N=227)
感染症および寄生虫症（続き）				
肺炎	Overall	2(0.9)	-	1(0.4)
	Mild	-	-	-
	Moderate	1(0.4)	-	-
	Severe	1(0.4)	-	1(0.4)
結膜炎	Overall	1(0.4)	-	1(0.4)
	Mild	1(0.4)	-	1(0.4)
	Moderate	-	-	-
	Severe	-	-	-
膀胱炎	Overall	-	-	2(0.9)
	Mild	-	-	1(0.4)
	Moderate	-	-	1(0.4)
	Severe	-	-	-
丹毒	Overall	1(0.4)	1(0.4)	-
	Mild	-	1(0.4)	-
	Moderate	1(0.4)	-	-
	Severe	-	-	-
帯状疱疹	Overall	1(0.4)	1(0.4)	-
	Mild	1(0.4)	-	-
	Moderate	-	1(0.4)	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.2.1.5

表 2.7.4.7-付録-20　有害事象の程度別発現頻度（122 試験）（19/60）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=229)	 1 mg (N=231)	 Entacapone (N=227)
感染症および寄生虫症（続き）				
細菌尿	Overall	-	1(0.4)	-
	Mild	-	-	-
	Moderate	-	1(0.4)	-
	Severe	-	-	-
蜂巣炎	Overall	-	1(0.4)	-
	Mild	-	1(0.4)	-
	Moderate	-	-	-
	Severe	-	-	-
皮膚真菌感染	Overall	-	-	1(0.4)
	Mild	-	-	1(0.4)
	Moderate	-	-	-
	Severe	-	-	-
胃腸炎	Overall	-	-	1(0.4)
	Mild	-	-	1(0.4)
	Moderate	-	-	-
	Severe	-	-	-
サルモネラ菌性胃腸炎	Overall	-	-	1(0.4)
	Mild	-	-	-
	Moderate	-	-	1(0.4)
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.2.1.5

表 2.7.4.7-付録-20　有害事象の程度別発現頻度（122 試験）（20/60）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=229)	 1 mg (N=231)	 Entacapone (N=227)
感染症および寄生虫症（続き）				
ウイルス性胃腸炎	Overall	-	1(0.4)	-
	Mild	-	-	-
	Moderate	-	1(0.4)	-
	Severe	-	-	-
単純ヘルペス	Overall	-	1(0.4)	-
	Mild	-	1(0.4)	-
	Moderate	-	-	-
	Severe	-	-	-
クレブシエラ性敗血症	Overall	-	1(0.4)	-
	Mild	-	-	-
	Moderate	-	-	-
	Severe	-	1(0.4)	-
迷路炎	Overall	-	-	1(0.4)
	Mild	-	-	-
	Moderate	-	-	1(0.4)
	Severe	-	-	-
喉頭炎	Overall	1(0.4)	-	-
	Mild	-	-	-
	Moderate	1(0.4)	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.2.1.5

表 2.7.4.7-付録-20　有害事象の程度別発現頻度（122 試験）（21/60）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=229)	 1 mg (N=231)	 Entacapone (N=227)
感染症および寄生虫症（続き）				
細菌性髄膜炎	Overall	-	1(0.4)	-
	Mild	-	-	-
	Moderate	-	-	-
	Severe	-	1(0.4)	-
爪真菌症	Overall	-	-	1(0.4)
	Mild	-	-	1(0.4)
	Moderate	-	-	-
	Severe	-	-	-
口腔カンジダ症	Overall	-	-	1(0.4)
	Mild	-	-	1(0.4)
	Moderate	-	-	-
	Severe	-	-	-
敗血症	Overall	-	1(0.4)	-
	Mild	-	-	-
	Moderate	-	-	-
	Severe	-	1(0.4)	-
皮膚感染	Overall	1(0.4)	-	-
	Mild	1(0.4)	-	-
	Moderate	-	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.2.1.5

表 2.7.4.7-付録-20　有害事象の程度別発現頻度（122 試験）（22/60）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=229)	 1 mg (N=231)	 Entacapone (N=227)
感染症および寄生虫症（続き）				
扁桃炎	Overall	-	-	1(0.4)
	Mild	-	-	-
	Moderate	-	-	1(0.4)
	Severe	-	-	-
歯感染	Overall	-	-	1(0.4)
	Mild	-	-	1(0.4)
	Moderate	-	-	-
	Severe	-	-	-
上気道感染	Overall	-	1(0.4)	-
	Mild	-	1(0.4)	-
	Moderate	-	-	-
	Severe	-	-	-
傷害、中毒および処置合併症	Overall	4(1.7)	6(2.6)	16(7.0)
	Mild	2(0.9)	4(1.7)	3(1.3)
	Moderate	1(0.4)	2(0.9)	11(4.8)
	Severe	1(0.4)	-	2(0.9)
転倒	Overall	2(0.9)	2(0.9)	7(3.1)
	Mild	1(0.4)	2(0.9)	2(0.9)
	Moderate	-	-	5(2.2)
	Severe	1(0.4)	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.2.1.5

表 2.7.4.7-付録-20　有害事象の程度別発現頻度（122 試験）（23/60）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=229)	 1 mg (N=231)	 Entacapone (N=227)
傷害、中毒および処置合併症（続き）				
頭部損傷	Overall	-	-	2(0.9)
	Mild	-	-	1(0.4)
	Moderate	-	-	-
	Severe	-	-	1(0.4)
関節脱臼	Overall	-	1(0.4)	1(0.4)
	Mild	-	1(0.4)	-
	Moderate	-	-	1(0.4)
	Severe	-	-	-
骨盤骨折	Overall	-	-	2(0.9)
	Mild	-	-	-
	Moderate	-	-	2(0.9)
	Severe	-	-	-
肋骨骨折	Overall	-	-	2(0.9)
	Mild	-	-	-
	Moderate	-	-	2(0.9)
	Severe	-	-	-
剥離骨折	Overall	1(0.4)	-	-
	Mild	1(0.4)	-	-
	Moderate	-	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.2.1.5

表 2.7.4.7-付録-20　有害事象の程度別発現頻度（122 試験）（24/60）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=229)	 1 mg (N=231)	 Entacapone (N=227)
傷害、中毒および処置合併症（続き）				
挫傷	Overall	-	-	1(0.4)
	Mild	-	-	-
	Moderate	-	-	1(0.4)
	Severe	-	-	-
上顎炎	Overall	-	-	1(0.4)
	Mild	-	-	-
	Moderate	-	-	1(0.4)
	Severe	-	-	-
大腿骨骨折	Overall	-	-	1(0.4)
	Mild	-	-	-
	Moderate	-	-	1(0.4)
	Severe	-	-	-
手骨折	Overall	-	-	1(0.4)
	Mild	-	-	-
	Moderate	-	-	1(0.4)
	Severe	-	-	-
股関節部骨折	Overall	-	-	1(0.4)
	Mild	-	-	-
	Moderate	-	-	-
	Severe	-	-	1(0.4)

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.2.1.5

表 2.7.4.7-付録-20　有害事象の程度別発現頻度（122 試験）（25/60）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=229)	 1 mg (N=231)	 Entacapone (N=227)
傷害、中毒および処置合併症（続き）				
顎の骨折	Overall	-	-	1(0.4)
	Mild	-	-	-
	Moderate	-	-	-
	Severe	-	-	1(0.4)
裂傷	Overall	-	-	1(0.4)
	Mild	-	-	1(0.4)
	Moderate	-	-	-
	Severe	-	-	-
靭帯捻挫	Overall	-	1(0.4)	-
	Mild	-	-	-
	Moderate	-	1(0.4)	-
	Severe	-	-	-
処置後浮腫	Overall	-	1(0.4)	-
	Mild	-	1(0.4)	-
	Moderate	-	-	-
	Severe	-	-	-
熱傷	Overall	-	1(0.4)	-
	Mild	-	-	-
	Moderate	-	1(0.4)	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.2.1.5

表 2.7.4.7-付録-20　有害事象の程度別発現頻度（122 試験）（26/60）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=229)	 1 mg (N=231)	 Entacapone (N=227)
傷害、中毒および処置合併症（続き）				
手首関節骨折	Overall	1(0.4)	-	-
	Mild	-	-	-
	Moderate	1(0.4)	-	-
	Severe	-	-	-
臨床検査	Overall	5(2.2)	9(3.9)	8(3.5)
	Mild	4(1.7)	4(1.7)	7(3.1)
	Moderate	1(0.4)	4(1.7)	1(0.4)
	Severe	-	1(0.4)	-
体重減少	Overall	2(0.9)	2(0.9)	5(2.2)
	Mild	1(0.4)	1(0.4)	5(2.2)
	Moderate	1(0.4)	1(0.4)	-
	Severe	-	-	-
細菌検査陽性	Overall	1(0.4)	1(0.4)	-
	Mild	1(0.4)	1(0.4)	-
	Moderate	-	-	-
	Severe	-	-	-
尿検査異常	Overall	-	-	2(0.9)
	Mild	-	-	2(0.9)
	Moderate	-	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.2.1.5

表 2.7.4.7-付録-20　有害事象の程度別発現頻度（122 試験）（27/60）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=229)	 1 mg (N=231)	 Entacapone (N=227)
臨床検査（続き）				
尿量増加	Overall	1(0.4)	1(0.4)	-
	Mild	1(0.4)	1(0.4)	-
	Moderate	-	-	-
	Severe	-	-	-
体重増加	Overall	-	2(0.9)	-
	Mild	-	-	-
	Moderate	-	2(0.9)	-
	Severe	-	-	-
アラニンアミノトランスフェラーゼ増加	Overall	-	1(0.4)	-
	Mild	-	1(0.4)	-
	Moderate	-	-	-
	Severe	-	-	-
気管支吸引	Overall	-	1(0.4)	-
	Mild	-	-	-
	Moderate	-	-	-
	Severe	-	1(0.4)	-
血中アルカリホスファターゼ異常	Overall	-	-	1(0.4)
	Mild	-	-	1(0.4)
	Moderate	-	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.2.1.5

表 2.7.4.7-付録-20　有害事象の程度別発現頻度（122 試験）（28/60）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=229)	 1 mg (N=231)	 Entacapone (N=227)
臨床検査（続き）				
血中アルカリホスファターゼ増加	Overall	-	-	1(0.4)
	Mild	-	-	1(0.4)
	Moderate	-	-	-
	Severe	-	-	-
血中クレアチニン異常	Overall	-	-	1(0.4)
	Mild	-	-	1(0.4)
	Moderate	-	-	-
	Severe	-	-	-
血圧上昇	Overall	-	-	1(0.4)
	Mild	-	-	-
	Moderate	-	-	1(0.4)
	Severe	-	-	-
心電図ＱＲＳ群延長	Overall	-	1(0.4)	-
	Mild	-	1(0.4)	-
	Moderate	-	-	-
	Severe	-	-	-
消化管内視鏡検査	Overall	-	1(0.4)	-
	Mild	-	-	-
	Moderate	-	1(0.4)	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.2.1.5

表 2.7.4.7-付録-20　有害事象の程度別発現頻度（122 試験）（29/60）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=229)	 1 mg (N=231)	 Entacapone (N=227)
臨床検査（続き）				
尿中赤血球陽性	Overall	1(0.4)	-	-
	Mild	1(0.4)	-	-
	Moderate	-	-	-
	Severe	-	-	-
尿中白血球陽性	Overall	1(0.4)	-	-
	Mild	1(0.4)	-	-
	Moderate	-	-	-
	Severe	-	-	-
代謝および栄養障害	Overall	8(3.5)	5(2.2)	6(2.6)
	Mild	4(1.7)	3(1.3)	5(2.2)
	Moderate	4(1.7)	2(0.9)	-
	Severe	-	-	1(0.4)
高コレステロール血症	Overall	1(0.4)	2(0.9)	3(1.3)
	Mild	1(0.4)	2(0.9)	3(1.3)
	Moderate	-	-	-
	Severe	-	-	-
食欲亢進	Overall	1(0.4)	1(0.4)	1(0.4)
	Mild	1(0.4)	1(0.4)	1(0.4)
	Moderate	-	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.2.1.5

表 2.7.4.7-付録-20　有害事象の程度別発現頻度（122 試験）（30/60）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=229)	 1 mg (N=231)	 Entacapone (N=227)
代謝および栄養障害（続き）				
食欲減退	Overall	1(0.4)	-	1(0.4)
	Mild	1(0.4)	-	1(0.4)
	Moderate	-	-	-
	Severe	-	-	-
脱水	Overall	2(0.9)	-	-
	Mild	-	-	-
	Moderate	2(0.9)	-	-
	Severe	-	-	-
痛風	Overall	-	2(0.9)	-
	Mild	-	-	-
	Moderate	-	2(0.9)	-
	Severe	-	-	-
高カリウム血症	Overall	2(0.9)	-	-
	Mild	-	-	-
	Moderate	2(0.9)	-	-
	Severe	-	-	-
高カルシウム血症	Overall	1(0.4)	-	-
	Mild	1(0.4)	-	-
	Moderate	-	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.2.1.5

表 2.7.4.7-付録-20　有害事象の程度別発現頻度（122 試験）（31/60）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=229)	 1 mg (N=231)	 Entacapone (N=227)
代謝および栄養障害（続き）				
低カルシウム血症	Overall	1(0.4)	-	-
	Mild	1(0.4)	-	-
	Moderate	-	-	-
	Severe	-	-	-
低カリウム血症	Overall	-	-	1(0.4)
	Mild	-	-	-
	Moderate	-	-	-
	Severe	-	-	1(0.4)
筋骨格系および結合組織障害	Overall	12(5.2)	12(5.2)	11(4.8)
	Mild	4(1.7)	3(1.3)	9(4.0)
	Moderate	8(3.5)	8(3.5)	2(0.9)
	Severe	-	1(0.4)	-
背部痛	Overall	4(1.7)	3(1.3)	2(0.9)
	Mild	2(0.9)	-	1(0.4)
	Moderate	2(0.9)	3(1.3)	1(0.4)
	Severe	-	-	-
筋痙縮	Overall	1(0.4)	1(0.4)	1(0.4)
	Mild	-	-	1(0.4)
	Moderate	1(0.4)	1(0.4)	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.2.1.5

表 2.7.4.7-付録-20　有害事象の程度別発現頻度（122 試験）（32/60）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=229)	 1 mg (N=231)	 Entacapone (N=227)
筋骨格系および結合組織障害（続き）				
関節痛	Overall	-	-	2(0.9)
	Mild	-	-	2(0.9)
	Moderate	-	-	-
	Severe	-	-	-
関節腫脹	Overall	1(0.4)	-	1(0.4)
	Mild	1(0.4)	-	1(0.4)
	Moderate	-	-	-
	Severe	-	-	-
筋骨格痛	Overall	1(0.4)	1(0.4)	-
	Mild	-	-	-
	Moderate	1(0.4)	1(0.4)	-
	Severe	-	-	-
筋肉痛	Overall	-	1(0.4)	1(0.4)
	Mild	-	-	1(0.4)
	Moderate	-	1(0.4)	-
	Severe	-	-	-
頚部痛	Overall	-	1(0.4)	1(0.4)
	Mild	-	1(0.4)	1(0.4)
	Moderate	-	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.2.1.5

表 2.7.4.7-付録-20　有害事象の程度別発現頻度（122 試験）（33/60）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=229)	 1 mg (N=231)	 Entacapone (N=227)
筋骨格系および結合組織障害（続き）				
変形性関節症	Overall	1(0.4)	-	1(0.4)
	Mild	-	-	1(0.4)
	Moderate	1(0.4)	-	-
	Severe	-	-	-
関節炎	Overall	1(0.4)	-	-
	Mild	1(0.4)	-	-
	Moderate	-	-	-
	Severe	-	-	-
椎間板障害	Overall	1(0.4)	-	-
	Mild	-	-	-
	Moderate	1(0.4)	-	-
	Severe	-	-	-
四肢不快感	Overall	1(0.4)	-	-
	Mild	1(0.4)	-	-
	Moderate	-	-	-
	Severe	-	-	-
筋拘縮	Overall	1(0.4)	-	-
	Mild	-	-	-
	Moderate	1(0.4)	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.2.1.5

表 2.7.4.7-付録-20　有害事象の程度別発現頻度（122 試験）（34/60）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=229)	 1 mg (N=231)	 Entacapone (N=227)
筋骨格系および結合組織障害（続き）				
筋固縮	Overall	1(0.4)	-	-
	Mild	-	-	-
	Moderate	1(0.4)	-	-
	Severe	-	-	-
筋骨格系胸痛	Overall	-	1(0.4)	-
	Mild	-	-	-
	Moderate	-	-	-
	Severe	-	1(0.4)	-
筋骨格硬直	Overall	-	-	1(0.4)
	Mild	-	-	1(0.4)
	Moderate	-	-	-
	Severe	-	-	-
筋炎	Overall	-	1(0.4)	-
	Mild	-	1(0.4)	-
	Moderate	-	-	-
	Severe	-	-	-
骨粗鬆症	Overall	-	1(0.4)	-
	Mild	-	1(0.4)	-
	Moderate	-	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.2.1.5

表 2.7.4.7-付録-20　有害事象の程度別発現頻度（122 試験）（35/60）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=229)	 1 mg (N=231)	 Entacapone (N=227)
筋骨格系および結合組織障害（続き）				
四肢痛	Overall	-	1(0.4)	-
	Mild	-	-	-
	Moderate	-	1(0.4)	-
	Severe	-	-	-
リウマチ性障害	Overall	-	-	1(0.4)
	Mild	-	-	-
	Moderate	-	-	1(0.4)
	Severe	-	-	-
脊柱管狭窄症	Overall	-	1(0.4)	-
	Mild	-	-	-
	Moderate	-	1(0.4)	-
	Severe	-	-	-
斜頚	Overall	-	1(0.4)	-
	Mild	-	-	-
	Moderate	-	1(0.4)	-
	Severe	-	-	-
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	Overall	2(0.9)	4(1.7)	3(1.3)
	Mild	1(0.4)	2(0.9)	1(0.4)
	Moderate	-	1(0.4)	1(0.4)
	Severe	1(0.4)	1(0.4)	1(0.4)

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.2.1.5

表 2.7.4.7-付録-20　有害事象の程度別発現頻度（122 試験）（36/60）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=229)	 1 mg (N=231)	 Entacapone (N=227)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）（続き）				
メラノサイト性母斑	Overall	-	-	2(0.9)
	Mild	-	-	1(0.4)
	Moderate	-	-	1(0.4)
	Severe	-	-	-
胃血管腫	Overall	-	1(0.4)	-
	Mild	-	-	-
	Moderate	-	1(0.4)	-
	Severe	-	-	-
カポジ肉腫	Overall	-	1(0.4)	-
	Mild	-	-	-
	Moderate	-	-	-
	Severe	-	1(0.4)	-
表皮内悪性黒色腫	Overall	1(0.4)	-	-
	Mild	1(0.4)	-	-
	Moderate	-	-	-
	Severe	-	-	-
前立腺癌	Overall	-	-	1(0.4)
	Mild	-	-	-
	Moderate	-	-	-
	Severe	-	-	1(0.4)

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.2.1.5

表 2.7.4.7-付録-20　有害事象の程度別発現頻度（122 試験）（37/60）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=229)	 1 mg (N=231)	 Entacapone (N=227)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）（続き）				
前立腺腺腫	Overall	-	1(0.4)	-
	Mild	-	1(0.4)	-
	Moderate	-	-	-
	Severe	-	-	-
脂漏性角化症	Overall	-	1(0.4)	-
	Mild	-	1(0.4)	-
	Moderate	-	-	-
	Severe	-	-	-
扁平上皮癌	Overall	1(0.4)	-	-
	Mild	-	-	-
	Moderate	-	-	-
	Severe	1(0.4)	-	-
神経系障害	Overall	33(14.4)	34(14.7)	36(15.9)
	Mild	6(2.6)	12(5.2)	17(7.5)
	Moderate	24(10.5)	20(8.7)	18(7.9)
	Severe	3(1.3)	2(0.9)	1(0.4)
ジスキネジア	Overall	9(3.9)	12(5.2)	14(6.2)
	Mild	2(0.9)	2(0.9)	6(2.6)
	Moderate	6(2.6)	10(4.3)	8(3.5)
	Severe	1(0.4)	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.2.1.5

表 2.7.4.7-付録-20　有害事象の程度別発現頻度（122 試験）（38/60）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=229)	 1 mg (N=231)	 Entacapone (N=227)
神経系障害（続き）				
浮動性めまい	Overall	4(1.7)	5(2.2)	5(2.2)
	Mild	2(0.9)	3(1.3)	4(1.8)
	Moderate	2(0.9)	2(0.9)	1(0.4)
	Severe	-	-	-
頭痛	Overall	8(3.5)	2(0.9)	3(1.3)
	Mild	2(0.9)	2(0.9)	3(1.3)
	Moderate	6(2.6)	-	-
	Severe	-	-	-
ジストニア	Overall	1(0.4)	5(2.2)	2(0.9)
	Mild	-	-	2(0.9)
	Moderate	1(0.4)	5(2.2)	-
	Severe	-	-	-
オンオフ現象	Overall	3(1.3)	2(0.9)	3(1.3)
	Mild	-	1(0.4)	-
	Moderate	2(0.9)	1(0.4)	3(1.3)
	Severe	1(0.4)	-	-
傾眠	Overall	1(0.4)	2(0.9)	3(1.3)
	Mild	1(0.4)	1(0.4)	3(1.3)
	Moderate	-	1(0.4)	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.2.1.5

表 2.7.4.7-付録-20　有害事象の程度別発現頻度（122 試験）（39/60）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=229)	 1 mg (N=231)	 Entacapone (N=227)
神経系障害（続き）				
パーキンソン病	Overall	2(0.9)	1(0.4)	2(0.9)
	Mild	1(0.4)	1(0.4)	-
	Moderate	-	-	2(0.9)
	Severe	1(0.4)	-	-
錯感覚	Overall	2(0.9)	-	2(0.9)
	Mild	-	-	1(0.4)
	Moderate	2(0.9)	-	1(0.4)
	Severe	-	-	-
坐骨神経痛	Overall	1(0.4)	3(1.3)	-
	Mild	-	3(1.3)	-
	Moderate	1(0.4)	-	-
	Severe	-	-	-
平衡障害	Overall	-	1(0.4)	2(0.9)
	Mild	-	-	1(0.4)
	Moderate	-	1(0.4)	1(0.4)
	Severe	-	-	-
筋緊張亢進	Overall	2(0.9)	1(0.4)	-
	Mild	-	1(0.4)	-
	Moderate	2(0.9)	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.2.1.5

表 2.7.4.7-付録-20　有害事象の程度別発現頻度（122 試験）（40/60）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=229)	 1 mg (N=231)	 Entacapone (N=227)
神経系障害（続き）				
失神	Overall	1(0.4)	2(0.9)	-
	Mild	-	-	-
	Moderate	1(0.4)	-	-
	Severe	-	2(0.9)	-
パーキンソニズム	Overall	1(0.4)	-	1(0.4)
	Mild	-	-	-
	Moderate	1(0.4)	-	-
	Severe	-	-	1(0.4)
振戦	Overall	-	1(0.4)	1(0.4)
	Mild	-	-	1(0.4)
	Moderate	-	1(0.4)	-
	Severe	-	-	-
無動	Overall	1(0.4)	-	-
	Mild	-	-	-
	Moderate	1(0.4)	-	-
	Severe	-	-	-
運動緩慢	Overall	1(0.4)	-	-
	Mild	-	-	-
	Moderate	1(0.4)	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.2.1.5

表 2.7.4.7-付録-20　有害事象の程度別発現頻度（122 試験）（41/60）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=229)	 1 mg (N=231)	 Entacapone (N=227)
神経系障害（続き）				
脳血管不全	Overall	1(0.4)	-	-
	Mild	-	-	-
	Moderate	-	-	-
	Severe	1(0.4)	-	-
注意力障害	Overall	-	-	1(0.4)
	Mild	-	-	1(0.4)
	Moderate	-	-	-
	Severe	-	-	-
体位性めまい	Overall	-	1(0.4)	-
	Mild	-	-	-
	Moderate	-	1(0.4)	-
	Severe	-	-	-
構語障害	Overall	-	-	1(0.4)
	Mild	-	-	1(0.4)
	Moderate	-	-	-
	Severe	-	-	-
味覚異常	Overall	1(0.4)	-	-
	Mild	1(0.4)	-	-
	Moderate	-	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.2.1.5

表 2.7.4.7-付録-20　有害事象の程度別発現頻度（122 試験）（42/60）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=229)	 1 mg (N=231)	 Entacapone (N=227)
神経系障害（続き）				
顔面痙攣	Overall	-	-	1(0.4)
	Mild	-	-	-
	Moderate	-	-	1(0.4)
	Severe	-	-	-
運動過多	Overall	-	-	1(0.4)
	Mild	-	-	-
	Moderate	-	-	1(0.4)
	Severe	-	-	-
過眠症	Overall	-	1(0.4)	-
	Mild	-	-	-
	Moderate	-	1(0.4)	-
	Severe	-	-	-
虚血性脳卒中	Overall	1(0.4)	-	-
	Mild	-	-	-
	Moderate	1(0.4)	-	-
	Severe	-	-	-
嗜眠	Overall	1(0.4)	-	-
	Mild	-	-	-
	Moderate	1(0.4)	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.2.1.5

表 2.7.4.7-付録-20　有害事象の程度別発現頻度（122 試験）（43/60）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=229)	 1 mg (N=231)	 Entacapone (N=227)
神経系障害（続き）				
意識消失	Overall	1(0.4)	-	-
	Mild	-	-	-
	Moderate	1(0.4)	-	-
	Severe	-	-	-
記憶障害	Overall	-	-	1(0.4)
	Mild	-	-	1(0.4)
	Moderate	-	-	-
	Severe	-	-	-
片頭痛	Overall	-	1(0.4)	-
	Mild	-	1(0.4)	-
	Moderate	-	-	-
	Severe	-	-	-
多発性単ニューロパチー	Overall	1(0.4)	-	-
	Mild	-	-	-
	Moderate	1(0.4)	-	-
	Severe	-	-	-
不全単麻痺	Overall	-	-	1(0.4)
	Mild	-	-	1(0.4)
	Moderate	-	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.2.1.5

表 2.7.4.7-付録-20　有害事象の程度別発現頻度（122 試験）（44/60）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=229)	 1 mg (N=231)	 Entacapone (N=227)
神経系障害（続き）				
多発性硬化症再発	Overall	-	1(0.4)	-
	Mild	-	1(0.4)	-
	Moderate	-	-	-
	Severe	-	-	-
眼振	Overall	-	1(0.4)	-
	Mild	-	-	-
	Moderate	-	1(0.4)	-
	Severe	-	-	-
精神運動亢進	Overall	-	1(0.4)	-
	Mild	-	-	-
	Moderate	-	1(0.4)	-
	Severe	-	-	-
神経根痛	Overall	-	-	1(0.4)
	Mild	-	-	-
	Moderate	-	-	1(0.4)
	Severe	-	-	-
会話障害	Overall	-	1(0.4)	-
	Mild	-	1(0.4)	-
	Moderate	-	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.2.1.5

表 2.7.4.7-付録-20　有害事象の程度別発現頻度（122 試験）（45/60）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=229)	 1 mg (N=231)	 Entacapone (N=227)
精神障害	Overall	26(11.4)	23(10.0)	25(11.0)
	Mild	17(7.4)	13(5.6)	16(7.0)
	Moderate	8(3.5)	9(3.9)	6(2.6)
	Severe	1(0.4)	1(0.4)	3(1.3)
うつ病	Overall	6(2.6)	7(3.0)	5(2.2)
	Mild	4(1.7)	5(2.2)	2(0.9)
	Moderate	2(0.9)	2(0.9)	2(0.9)
	Severe	-	-	1(0.4)
不眠症	Overall	5(2.2)	6(2.6)	7(3.1)
	Mild	5(2.2)	4(1.7)	5(2.2)
	Moderate	-	1(0.4)	2(0.9)
	Severe	-	1(0.4)	-
不安	Overall	8(3.5)	5(2.2)	2(0.9)
	Mild	4(1.7)	2(0.9)	1(0.4)
	Moderate	4(1.7)	3(1.3)	1(0.4)
	Severe	-	-	-
幻覚	Overall	1(0.4)	3(1.3)	8(3.5)
	Mild	1(0.4)	2(0.9)	6(2.6)
	Moderate	-	1(0.4)	1(0.4)
	Severe	-	-	1(0.4)
異常な夢	Overall	1(0.4)	2(0.9)	2(0.9)
	Mild	1(0.4)	2(0.9)	1(0.4)
	Moderate	-	-	1(0.4)
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.2.1.5

表 2.7.4.7-付録-20　有害事象の程度別発現頻度（122 試験）（46/60）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=229)	 1 mg (N=231)	 Entacapone (N=227)
精神障害（続き）				
幻視	Overall	2(0.9)	2(0.9)	1(0.4)
	Mild	1(0.4)	1(0.4)	-
	Moderate	1(0.4)	1(0.4)	-
	Severe	-	-	1(0.4)
錯乱状態	Overall	1(0.4)	1(0.4)	2(0.9)
	Mild	-	1(0.4)	-
	Moderate	1(0.4)	-	2(0.9)
	Severe	-	-	-
睡眠障害	Overall	-	1(0.4)	1(0.4)
	Mild	-	-	1(0.4)
	Moderate	-	1(0.4)	-
	Severe	-	-	-
抑うつ気分を伴う適応障害	Overall	-	-	1(0.4)
	Mild	-	-	1(0.4)
	Moderate	-	-	-
	Severe	-	-	-
注意欠陥多動性障害	Overall	-	1(0.4)	-
	Mild	-	-	-
	Moderate	-	1(0.4)	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.2.1.5

表 2.7.4.7-付録-20　有害事象の程度別発現頻度（122 試験）（47/60）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=229)	 1 mg (N=231)	 Entacapone (N=227)
精神障害（続き）				
自殺既遂	Overall	1(0.4)	-	-
	Mild	-	-	-
	Moderate	-	-	-
	Severe	1(0.4)	-	-
抑うつ気分	Overall	-	1(0.4)	-
	Mild	-	-	-
	Moderate	-	1(0.4)	-
	Severe	-	-	-
抑うつ症状	Overall	1(0.4)	-	-
	Mild	1(0.4)	-	-
	Moderate	-	-	-
	Severe	-	-	-
言葉もれ	Overall	-	-	1(0.4)
	Mild	-	-	1(0.4)
	Moderate	-	-	-
	Severe	-	-	-
悪夢	Overall	-	-	1(0.4)
	Mild	-	-	1(0.4)
	Moderate	-	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]　Statistical Analysis Report (5.3.5.3-1) Table 2.2.1.5

表 2.7.4.7-付録-20　有害事象の程度別発現頻度（122 試験）（48/60）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=229)	 1 mg (N=231)	 Entacapone (N=227)
精神障害（続き）				
パニック発作	Overall	1(0.4)	-	-
	Mild	-	-	-
	Moderate	1(0.4)	-	-
	Severe	-	-	-
自殺企図	Overall	-	-	1(0.4)
	Mild	-	-	-
	Moderate	-	-	-
	Severe	-	-	1(0.4)
腎および尿路障害	Overall	6(2.6)	8(3.5)	19(8.4)
	Mild	4(1.7)	5(2.2)	12(5.3)
	Moderate	2(0.9)	2(0.9)	5(2.2)
	Severe	-	1(0.4)	2(0.9)
着色尿	Overall	-	-	14(6.2)
	Mild	-	-	9(4.0)
	Moderate	-	-	4(1.8)
	Severe	-	-	1(0.4)
尿閉	Overall	2(0.9)	1(0.4)	-
	Mild	-	1(0.4)	-
	Moderate	2(0.9)	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.2.1.5

表 2.7.4.7-付録-20　有害事象の程度別発現頻度（122 試験）（49/60）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=229)	 1 mg (N=231)	 Entacapone (N=227)
腎および尿路障害（続き）				
排尿困難	Overall	-	2(0.9)	-
	Mild	-	1(0.4)	-
	Moderate	-	-	-
	Severe	-	1(0.4)	-
尿意切迫	Overall	1(0.4)	1(0.4)	-
	Mild	1(0.4)	1(0.4)	-
	Moderate	-	-	-
	Severe	-	-	-
頻尿	Overall	1(0.4)	1(0.4)	-
	Mild	1(0.4)	1(0.4)	-
	Moderate	-	-	-
	Severe	-	-	-
腎嚢胞	Overall	-	1(0.4)	1(0.4)
	Mild	-	1(0.4)	1(0.4)
	Moderate	-	-	-
	Severe	-	-	-
急性腎障害	Overall	-	1(0.4)	-
	Mild	-	-	-
	Moderate	-	1(0.4)	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.2.1.5

表 2.7.4.7-付録-20　有害事象の程度別発現頻度（122 試験）（50/60）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=229)	 1 mg (N=231)	 Entacapone (N=227)
腎および尿路障害（続き）				
無尿	Overall	-	1(0.4)	-
	Mild	-	-	-
	Moderate	-	-	-
	Severe	-	1(0.4)	-
血尿	Overall	-	1(0.4)	-
	Mild	-	1(0.4)	-
	Moderate	-	-	-
	Severe	-	-	-
失禁	Overall	-	-	1(0.4)
	Mild	-	-	-
	Moderate	-	-	-
	Severe	-	-	1(0.4)
腎結石症	Overall	-	-	1(0.4)
	Mild	-	-	1(0.4)
	Moderate	-	-	-
	Severe	-	-	-
夜間頻尿	Overall	-	-	1(0.4)
	Mild	-	-	-
	Moderate	-	-	1(0.4)
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.2.1.5

表 2.7.4.7-付録-20　有害事象の程度別発現頻度（122 試験）（51/60）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=229)	 1 mg (N=231)	 Entacapone (N=227)
腎および尿路障害（続き）				
腎盂腎杯拡張症	Overall	-	1(0.4)	-
	Mild	-	1(0.4)	-
	Moderate	-	-	-
	Severe	-	-	-
腎萎縮	Overall	-	-	1(0.4)
	Mild	-	-	1(0.4)
	Moderate	-	-	-
	Severe	-	-	-
腎仙痛	Overall	-	1(0.4)	-
	Mild	-	-	-
	Moderate	-	1(0.4)	-
	Severe	-	-	-
腎不全	Overall	1(0.4)	-	-
	Mild	1(0.4)	-	-
	Moderate	-	-	-
	Severe	-	-	-
尿失禁	Overall	1(0.4)	-	-
	Mild	1(0.4)	-	-
	Moderate	-	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.2.1.5

表 2.7.4.7-付録-20　有害事象の程度別発現頻度（122 試験）（52/60）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=229)	 1 mg (N=231)	 Entacapone (N=227)
腎および尿路障害（続き）				
尿路閉塞	Overall	1(0.4)	-	-
	Mild	1(0.4)	-	-
	Moderate	-	-	-
	Severe	-	-	-
生殖系および乳房障害	Overall	1(0.4)	-	1(0.4)
	Mild	1(0.4)	-	1(0.4)
	Moderate	-	-	-
	Severe	-	-	-
良性前立腺肥大症	Overall	1(0.4)	-	-
	Mild	1(0.4)	-	-
	Moderate	-	-	-
	Severe	-	-	-
勃起不全	Overall	-	-	1(0.4)
	Mild	-	-	1(0.4)
	Moderate	-	-	-
	Severe	-	-	-
呼吸器、胸郭および縦隔障害	Overall	6(2.6)	7(3.0)	3(1.3)
	Mild	3(1.3)	4(1.7)	-
	Moderate	2(0.9)	2(0.9)	2(0.9)
	Severe	1(0.4)	1(0.4)	1(0.4)

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.2.1.5

表 2.7.4.7-付録-20　有害事象の程度別発現頻度（122 試験）（53/60）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=229)	 1 mg (N=231)	 Entacapone (N=227)
呼吸器、胸郭および縦隔障害（続き）				
咳嗽	Overall	1(0.4)	2(0.9)	-
	Mild	1(0.4)	2(0.9)	-
	Moderate	-	-	-
	Severe	-	-	-
呼吸困難	Overall	2(0.9)	1(0.4)	-
	Mild	-	1(0.4)	-
	Moderate	1(0.4)	-	-
	Severe	1(0.4)	-	-
肺塞栓症	Overall	-	1(0.4)	1(0.4)
	Mild	-	-	-
	Moderate	-	-	-
	Severe	-	1(0.4)	1(0.4)
喘息	Overall	-	1(0.4)	-
	Mild	-	1(0.4)	-
	Moderate	-	-	-
	Severe	-	-	-
喘息クリーゼ	Overall	-	-	1(0.4)
	Mild	-	-	-
	Moderate	-	-	1(0.4)
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.2.1.5

表 2.7.4.7-付録-20　有害事象の程度別発現頻度（122 試験）（54/60）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=229)	 1 mg (N=231)	 Entacapone (N=227)
呼吸器、胸郭および縦隔障害（続き）				
咽喉乾燥	Overall	1(0.4)	-	-
	Mild	1(0.4)	-	-
	Moderate	-	-	-
	Severe	-	-	-
労作性呼吸困難	Overall	-	1(0.4)	-
	Mild	-	-	-
	Moderate	-	1(0.4)	-
	Severe	-	-	-
発作性夜間呼吸困難	Overall	-	1(0.4)	-
	Mild	-	-	-
	Moderate	-	1(0.4)	-
	Severe	-	-	-
しゃっくり	Overall	1(0.4)	-	-
	Mild	1(0.4)	-	-
	Moderate	-	-	-
	Severe	-	-	-
鼻乾燥	Overall	1(0.4)	-	-
	Mild	1(0.4)	-	-
	Moderate	-	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.2.1.5

表 2.7.4.7-付録-20　有害事象の程度別発現頻度（122 試験）（55/60）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=229)	 1 mg (N=231)	 Entacapone (N=227)
呼吸器、胸郭および縦隔障害（続き）				
胸水	Overall	-	-	1(0.4)
	Mild	-	-	-
	Moderate	-	-	1(0.4)
	Severe	-	-	-
胸膜炎	Overall	1(0.4)	-	-
	Mild	-	-	-
	Moderate	1(0.4)	-	-
	Severe	-	-	-
皮膚および皮下組織障害	Overall	6(2.6)	6(2.6)	7(3.1)
	Mild	2(0.9)	5(2.2)	6(2.6)
	Moderate	4(1.7)	1(0.4)	1(0.4)
	Severe	-	-	-
湿疹	Overall	2(0.9)	1(0.4)	1(0.4)
	Mild	1(0.4)	1(0.4)	1(0.4)
	Moderate	1(0.4)	-	-
	Severe	-	-	-
多汗症	Overall	-	1(0.4)	2(0.9)
	Mild	-	1(0.4)	1(0.4)
	Moderate	-	-	1(0.4)
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.2.1.5

表 2.7.4.7-付録-20　有害事象の程度別発現頻度（122 試験）（56/60）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=229)	 1 mg (N=231)	 Entacapone (N=227)
皮膚および皮下組織障害（続き）				
紅斑	Overall	-	1(0.4)	1(0.4)
	Mild	-	-	1(0.4)
	Moderate	-	1(0.4)	-
	Severe	-	-	-
そう痒症	Overall	-	1(0.4)	1(0.4)
	Mild	-	1(0.4)	1(0.4)
	Moderate	-	-	-
	Severe	-	-	-
蕁麻疹	Overall	1(0.4)	-	1(0.4)
	Mild	-	-	1(0.4)
	Moderate	1(0.4)	-	-
	Severe	-	-	-
脱毛症	Overall	-	1(0.4)	-
	Mild	-	1(0.4)	-
	Moderate	-	-	-
	Severe	-	-	-
皮膚弛緩症	Overall	-	1(0.4)	-
	Mild	-	1(0.4)	-
	Moderate	-	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.2.1.5

表 2.7.4.7-付録-20　有害事象の程度別発現頻度（122 試験）（57/60）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=229)	 1 mg (N=231)	 Entacapone (N=227)
皮膚および皮下組織障害（続き）				
褥瘡性潰瘍	Overall	-	-	1(0.4)
	Mild	-	-	1(0.4)
	Moderate	-	-	-
	Severe	-	-	-
皮膚嚢腫	Overall	-	1(0.4)	-
	Mild	-	1(0.4)	-
	Moderate	-	-	-
	Severe	-	-	-
紅色症	Overall	1(0.4)	-	-
	Mild	1(0.4)	-	-
	Moderate	-	-	-
	Severe	-	-	-
分節ヒアリン血管炎	Overall	1(0.4)	-	-
	Mild	-	-	-
	Moderate	1(0.4)	-	-
	Severe	-	-	-
皮膚病変	Overall	1(0.4)	-	-
	Mild	-	-	-
	Moderate	1(0.4)	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.2.1.5

表 2.7.4.7-付録-20　有害事象の程度別発現頻度（122 試験）（58/60）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=229)	 1 mg (N=231)	 Entacapone (N=227)
皮膚および皮下組織障害（続き）				
血管炎性潰瘍	Overall	1(0.4)	-	-
	Mild	-	-	-
	Moderate	1(0.4)	-	-
	Severe	-	-	-
外科および内科処置	Overall	1(0.4)	2(0.9)	3(1.3)
	Mild	-	1(0.4)	2(0.9)
	Moderate	1(0.4)	1(0.4)	1(0.4)
	Severe	-	-	-
抜歯	Overall	-	1(0.4)	2(0.9)
	Mild	-	-	2(0.9)
	Moderate	-	1(0.4)	-
	Severe	-	-	-
心臓ペースメーカー挿入	Overall	-	1(0.4)	-
	Mild	-	1(0.4)	-
	Moderate	-	-	-
	Severe	-	-	-
歯科インプラント埋込み	Overall	-	-	1(0.4)
	Mild	-	-	-
	Moderate	-	-	1(0.4)
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.2.1.5

表 2.7.4.7-付録-20　有害事象の程度別発現頻度（122 試験）（59/60）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=229)	 1 mg (N=231)	 Entacapone (N=227)
外科および内科処置（続き）				
鼡径部ヘルニア修復	Overall	1(0.4)	-	-
	Mild	-	-	-
	Moderate	1(0.4)	-	-
	Severe	-	-	-
血管障害	Overall	13(5.7)	14(6.1)	11(4.8)
	Mild	8(3.5)	9(3.9)	8(3.5)
	Moderate	4(1.7)	5(2.2)	2(0.9)
	Severe	1(0.4)	-	1(0.4)
低血圧	Overall	6(2.6)	7(3.0)	3(1.3)
	Mild	5(2.2)	5(2.2)	3(1.3)
	Moderate	1(0.4)	2(0.9)	-
	Severe	-	-	-
高血圧	Overall	3(1.3)	2(0.9)	4(1.8)
	Mild	1(0.4)	1(0.4)	3(1.3)
	Moderate	2(0.9)	1(0.4)	1(0.4)
	Severe	-	-	-
起立性低血圧	Overall	-	4(1.7)	4(1.8)
	Mild	-	3(1.3)	2(0.9)
	Moderate	-	1(0.4)	1(0.4)
	Severe	-	-	1(0.4)

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.2.1.5

表 2.7.4.7-付録-20　有害事象の程度別発現頻度（122 試験）（60/60）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=229)	 1 mg (N=231)	 Entacapone (N=227)
血管障害（続き）				
血圧変動	Overall	-	2(0.9)	-
	Mild	-	-	-
	Moderate	-	2(0.9)	-
	Severe	-	-	-
大動脈解離	Overall	1(0.4)	-	-
	Mild	-	-	-
	Moderate	-	-	-
	Severe	1(0.4)	-	-
ほてり	Overall	1(0.4)	-	-
	Mild	1(0.4)	-	-
	Moderate	-	-	-
	Severe	-	-	-
高血圧クリーゼ	Overall	1(0.4)	-	-
	Mild	-	-	-
	Moderate	1(0.4)	-	-
	Severe	-	-	-
末梢静脈疾患	Overall	1(0.4)	-	-
	Mild	1(0.4)	-	-
	Moderate	-	-	-
	Severe	-	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.3-1) Table 2.2.1.5

表 2.7.4.7-付録-21　有害事象の程度別発現頻度（OCT-002 試験）（1/50）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) 1 mg (N=222)
Subjects with Any TEAEs	Overall	185(83.3)
	Mild	108(48.6)
	Moderate	65(29.3)
	Severe	12(5.4)
血液およびリンパ系障害	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-
貧血	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-
心臓障害	Overall	6(2.7)
	Mild	3(1.4)
	Moderate	3(1.4)
	Severe	-
心房細動	Overall	3(1.4)
	Mild	2(0.9)
	Moderate	1(0.5)
	Severe	-
急性心筋梗塞	Overall	1(0.5)
	Mild	-
	Moderate	1(0.5)
	Severe	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.2-1) Table 4.1.1.5

表 2.7.4.7-付録-21　有害事象の程度別発現頻度（OCT-002 試験）（2/50）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) 1 mg (N=222)
心臓障害（続き）		
狭心症	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-
心不全	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-
プリンツメタル狭心症	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-
洞結節機能不全	Overall	1(0.5)
	Mild	-
	Moderate	1(0.5)
	Severe	-
上室性期外収縮	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.2-1) Table 4.1.1.5

表 2.7.4.7-付録-21　有害事象の程度別発現頻度（OCT-002 試験）（3/50）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) 1 mg (N=222)
心臓障害（続き）		
上室性頻脈	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-
耳および迷路障害	Overall	3(1.4)
	Mild	1(0.5)
	Moderate	2(0.9)
	Severe	-
回転性めまい	Overall	2(0.9)
	Mild	-
	Moderate	2(0.9)
	Severe	-
耳鳴	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-
眼障害	Overall	11(5.0)
	Mild	9(4.1)
	Moderate	2(0.9)
	Severe	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.2-1) Table 4.1.1.5

表 2.7.4.7-付録-21　有害事象の程度別発現頻度（OCT-002 試験）（4/50）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) 1 mg (N=222)
眼障害（続き）		
結膜出血	Overall	2(0.9)
	Mild	2(0.9)
	Moderate	-
	Severe	-
眼充血	Overall	2(0.9)
	Mild	2(0.9)
	Moderate	-
	Severe	-
眼精疲労	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-
白内障	Overall	1(0.5)
	Mild	-
	Moderate	1(0.5)
	Severe	-
結膜充血	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.2-1) Table 4.1.1.5

表 2.7.4.7-付録-21　有害事象の程度別発現頻度（OCT-002 試験）（5/50）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) 1 mg (N=222)
眼障害（続き）		
眼乾燥	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-
眼潰瘍	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-
緑内障	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-
後嚢部混濁	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-
網膜剥離	Overall	1(0.5)
	Mild	-
	Moderate	1(0.5)
	Severe	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.2-1) Table 4.1.1.5

表 2.7.4.7-付録-21　有害事象の程度別発現頻度（OCT-002 試験）（6/50）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) 1 mg (N=222)
胃腸障害	Overall	49(22.1)
	Mild	44(19.8)
	Moderate	3(1.4)
	Severe	2(0.9)
齲歯	Overall	9(4.1)
	Mild	9(4.1)
	Moderate	-
	Severe	-
便秘	Overall	7(3.2)
	Mild	7(3.2)
	Moderate	-
	Severe	-
嘔吐	Overall	5(2.3)
	Mild	4(1.8)
	Moderate	-
	Severe	1(0.5)
胃炎	Overall	3(1.4)
	Mild	3(1.4)
	Moderate	-
	Severe	-
悪心	Overall	3(1.4)
	Mild	3(1.4)
	Moderate	-
	Severe	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.2-1) Table 4.1.1.5

表 2.7.4.7-付録-21　有害事象の程度別発現頻度（OCT-002 試験）（7/50）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) 1 mg (N=222)
胃腸障害（続き）		
上腹部痛	Overall	2(0.9)
	Mild	2(0.9)
	Moderate	-
	Severe	-
慢性胃炎	Overall	2(0.9)
	Mild	2(0.9)
	Moderate	-
	Severe	-
口内乾燥	Overall	2(0.9)
	Mild	2(0.9)
	Moderate	-
	Severe	-
消化不良	Overall	2(0.9)
	Mild	2(0.9)
	Moderate	-
	Severe	-
大腸ポリープ	Overall	2(0.9)
	Mild	2(0.9)
	Moderate	-
	Severe	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.2-1) Table 4.1.1.5

表 2.7.4.7-付録-21　有害事象の程度別発現頻度（OCT-002 試験）（8/50）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) 1 mg (N=222)
胃腸障害（続き）		
腹部不快感	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-
腹痛	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-
下腹部痛	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-
大腸炎	Overall	1(0.5)
	Mild	-
	Moderate	1(0.5)
	Severe	-
虚血性大腸炎	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.2-1) Table 4.1.1.5

表 2.7.4.7-付録-21　有害事象の程度別発現頻度（OCT-002 試験）（9/50）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) 1 mg (N=222)
胃腸障害（続き）		
下痢	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-
嚥下障害	Overall	1(0.5)
	Mild	-
	Moderate	1(0.5)
	Severe	-
食中毒	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-
胃潰瘍	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-
胃食道逆流性疾患	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.2-1) Table 4.1.1.5

表 2.7.4.7-付録-21　有害事象の程度別発現頻度（OCT-002 試験）（10/50）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) 1 mg (N=222)
胃腸障害（続き）		
歯肉痛	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-
裂孔ヘルニア	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-
口の感覚鈍麻	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-
イレウス	Overall	1(0.5)
	Mild	-
	Moderate	-
	Severe	1(0.5)
鼠径ヘルニア	Overall	1(0.5)
	Mild	-
	Moderate	1(0.5)
	Severe	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.2-1) Table 4.1.1.5

表 2.7.4.7-付録-21　有害事象の程度別発現頻度（OCT-002 試験）（11/50）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) 1 mg (N=222)
胃腸障害（続き）		
口唇びらん	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-
歯周病	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-
直腸炎	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-
直腸脱	Overall	1(0.5)
	Mild	-
	Moderate	1(0.5)
	Severe	-
口内炎	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.2-1) Table 4.1.1.5

表 2.7.4.7-付録-21　有害事象の程度別発現頻度（OCT-002 試験）（12/50）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) 1 mg (N=222)
胃腸障害（続き）		
歯の脱落	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-
歯痛	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-
一般・全身障害および投与部位の状態	Overall	17(7.7)
	Mild	12(5.4)
	Moderate	4(1.8)
	Severe	1(0.5)
発熱	Overall	5(2.3)
	Mild	4(1.8)
	Moderate	1(0.5)
	Severe	-
疲労	Overall	3(1.4)
	Mild	3(1.4)
	Moderate	-
	Severe	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.2-1) Table 4.1.1.5

表 2.7.4.7-付録-21　有害事象の程度別発現頻度（OCT-002 試験）（13/50）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) 1 mg (N=222)
一般・全身障害および投与部位の状態（続き）		
倦怠感	Overall	3(1.4)
	Mild	-
	Moderate	2(0.9)
	Severe	1(0.5)
末梢性浮腫	Overall	3(1.4)
	Mild	3(1.4)
	Moderate	-
	Severe	-
胸痛	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-
活動性低下	Overall	1(0.5)
	Mild	-
	Moderate	1(0.5)
	Severe	-
末梢腫脹	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.2-1) Table 4.1.1.5

表 2.7.4.7-付録-21　有害事象の程度別発現頻度（OCT-002 試験）（14/50）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) 1 mg (N=222)
肝胆道系障害	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-
肝機能異常	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-
感染症および寄生虫症	Overall	63(28.4)
	Mild	53(23.9)
	Moderate	9(4.1)
	Severe	1(0.5)
鼻咽頭炎	Overall	31(14.0)
	Mild	31(14.0)
	Moderate	-
	Severe	-
膀胱炎	Overall	5(2.3)
	Mild	4(1.8)
	Moderate	1(0.5)
	Severe	-
爪の皮膚糸状菌症	Overall	4(1.8)
	Mild	3(1.4)
	Moderate	1(0.5)
	Severe	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.2-1) Table 4.1.1.5

表 2.7.4.7-付録-21　有害事象の程度別発現頻度（OCT-002 試験）（15/50）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) 1 mg (N=222)
感染症および寄生虫症（続き）		
肺炎	Overall	4(1.8)
	Mild	2(0.9)
	Moderate	2(0.9)
	Severe	-
口角口唇炎	Overall	3(1.4)
	Mild	3(1.4)
	Moderate	-
	Severe	-
気管支炎	Overall	3(1.4)
	Mild	2(0.9)
	Moderate	1(0.5)
	Severe	-
インフルエンザ	Overall	3(1.4)
	Mild	2(0.9)
	Moderate	1(0.5)
	Severe	-
足部白癬	Overall	3(1.4)
	Mild	3(1.4)
	Moderate	-
	Severe	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.2-1) Table 4.1.1.5

表 2.7.4.7-付録-21　有害事象の程度別発現頻度（OCT-002 試験）（16/50）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) 1 mg (N=222)
感染症および寄生虫症（続き）		
上気道感染	Overall	3(1.4)
	Mild	1(0.5)
	Moderate	2(0.9)
	Severe	-
細菌感染	Overall	2(0.9)
	Mild	-
	Moderate	1(0.5)
	Severe	1(0.5)
結膜炎	Overall	2(0.9)
	Mild	2(0.9)
	Moderate	-
	Severe	-
胃腸炎	Overall	2(0.9)
	Mild	2(0.9)
	Moderate	-
	Severe	-
咽頭炎	Overall	2(0.9)
	Mild	2(0.9)
	Moderate	-
	Severe	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.2-1) Table 4.1.1.5

表 2.7.4.7-付録-21　有害事象の程度別発現頻度（OCT-002 試験）（17/50）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) 1 mg (N=222)
感染症および寄生虫症（続き）		
尿路感染	Overall	2(0.9)
	Mild	2(0.9)
	Moderate	-
	Severe	-
カンジダ感染	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-
蜂巣炎	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-
ノロウイルス性胃腸炎	Overall	1(0.5)
	Mild	-
	Moderate	1(0.5)
	Severe	-
歯肉炎	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.2-1) Table 4.1.1.5

表 2.7.4.7-付録-21　有害事象の程度別発現頻度（OCT-002 試験）（18/50）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) 1 mg (N=222)
感染症および寄生虫症（続き）		
ヘリコバクター感染	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-
帯状疱疹	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-
爪真菌症	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-
外耳炎	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-
中耳炎	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.2-1) Table 4.1.1.5

表 2.7.4.7-付録-21　有害事象の程度別発現頻度（OCT-002 試験）（19/50）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) 1 mg (N=222)
感染症および寄生虫症（続き）		
百日咳	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-
腎盂腎炎	Overall	1(0.5)
	Mild	-
	Moderate	1(0.5)
	Severe	-
鼻炎	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-
扁桃炎	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-
外陰部腟カンジダ症	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.2-1) Table 4.1.1.5

表 2.7.4.7-付録-21　有害事象の程度別発現頻度（OCT-002 試験）（20/50）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) 1 mg (N=222)
傷害、中毒および処置合併症	Overall	58(26.1)
	Mild	41(18.5)
	Moderate	12(5.4)
	Severe	5(2.3)
転倒	Overall	37(16.7)
	Mild	35(15.8)
	Moderate	2(0.9)
	Severe	-
挫傷	Overall	19(8.6)
	Mild	16(7.2)
	Moderate	3(1.4)
	Severe	-
靭帯捻挫	Overall	5(2.3)
	Mild	5(2.3)
	Moderate	-
	Severe	-
創傷	Overall	5(2.3)
	Mild	4(1.8)
	Moderate	1(0.5)
	Severe	-
脊椎圧迫骨折	Overall	4(1.8)
	Mild	2(0.9)
	Moderate	2(0.9)
	Severe	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.2-1) Table 4.1.1.5

表 2.7.4.7-付録-21　有害事象の程度別発現頻度（OCT-002 試験）（21/50）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) 1 mg (N=222)
傷害、中毒および処置合併症（続き）		
歯牙破折	Overall	4(1.8)
	Mild	4(1.8)
	Moderate	-
	Severe	-
大腿骨頚部骨折	Overall	3(1.4)
	Mild	-
	Moderate	1(0.5)
	Severe	2(0.9)
肋骨骨折	Overall	3(1.4)
	Mild	1(0.5)
	Moderate	2(0.9)
	Severe	-
大腿骨骨折	Overall	2(0.9)
	Mild	-
	Moderate	-
	Severe	2(0.9)
仙骨骨折	Overall	2(0.9)
	Mild	-
	Moderate	2(0.9)
	Severe	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.2-1) Table 4.1.1.5

表 2.7.4.7-付録-21　有害事象の程度別発現頻度（OCT-002 試験）（22/50）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) 1 mg (N=222)
傷害、中毒および処置合併症（続き）		
頭部損傷	Overall	2(0.9)
	Mild	2(0.9)
	Moderate	-
	Severe	-
交通事故	Overall	2(0.9)
	Mild	-
	Moderate	2(0.9)
	Severe	-
硬膜下血腫	Overall	2(0.9)
	Mild	1(0.5)
	Moderate	1(0.5)
	Severe	-
節足動物咬傷	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-
凍瘡	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.2-1) Table 4.1.1.5

表 2.7.4.7-付録-21　有害事象の程度別発現頻度（OCT-002 試験）（23/50）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) 1 mg (N=222)
傷害、中毒および処置合併症（続き）		
擦過傷	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-
関節損傷	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-
口唇損傷	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-
腰椎骨折	Overall	1(0.5)
	Mild	-
	Moderate	-
	Severe	1(0.5)
処置による疼痛	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.2-1) Table 4.1.1.5

表 2.7.4.7-付録-21　有害事象の程度別発現頻度（OCT-002 試験）（24/50）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) 1 mg (N=222)
傷害、中毒および処置合併症（続き）		
引っかき傷	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-
手首関節骨折	Overall	1(0.5)
	Mild	-
	Moderate	1(0.5)
	Severe	-
臨床検査	Overall	23(10.4)
	Mild	21(9.5)
	Moderate	2(0.9)
	Severe	-
血中クレアチンホスホキナーゼ増加	Overall	7(3.2)
	Mild	7(3.2)
	Moderate	-
	Severe	-
γ－グルタミルトランスフェラーゼ増加	Overall	4(1.8)
	Mild	4(1.8)
	Moderate	-
	Severe	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.2-1) Table 4.1.1.5

表 2.7.4.7-付録-21　有害事象の程度別発現頻度（OCT-002 試験）（25/50）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) 1 mg (N=222)
臨床検査（続き）		
血中アルカリホスファターゼ増加	Overall	3(1.4)
	Mild	3(1.4)
	Moderate	-
	Severe	-
血圧上昇	Overall	3(1.4)
	Mild	2(0.9)
	Moderate	1(0.5)
	Severe	-
血圧低下	Overall	2(0.9)
	Mild	2(0.9)
	Moderate	-
	Severe	-
血中乳酸脱水素酵素増加	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-
血中尿酸増加	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.2-1) Table 4.1.1.5

表 2.7.4.7-付録-21　有害事象の程度別発現頻度（OCT-002 試験）（26/50）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) 1 mg (N=222)
臨床検査（続き）		
肝機能検査値上昇	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-
便潜血	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-
尿中ケトン体陽性	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-
体重減少	Overall	1(0.5)
	Mild	-
	Moderate	1(0.5)
	Severe	-
代謝および栄養障害	Overall	20(9.0)
	Mild	15(6.8)
	Moderate	5(2.3)
	Severe	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.2-1) Table 4.1.1.5

表 2.7.4.7-付録-21　有害事象の程度別発現頻度（OCT-002 試験）（27/50）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) 1 mg (N=222)
代謝および栄養障害（続き）		
食欲減退	Overall	9(4.1)
	Mild	8(3.6)
	Moderate	1(0.5)
	Severe	-
脱水	Overall	7(3.2)
	Mild	4(1.8)
	Moderate	3(1.4)
	Severe	-
２型糖尿病	Overall	3(1.4)
	Mild	3(1.4)
	Moderate	-
	Severe	-
高尿酸血症	Overall	2(0.9)
	Mild	2(0.9)
	Moderate	-
	Severe	-
脂質異常症	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.2-1) Table 4.1.1.5

表 2.7.4.7-付録-21　有害事象の程度別発現頻度（OCT-002 試験）（28/50）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) 1 mg (N=222)
代謝および栄養障害（続き）		
低血糖	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-
低ナトリウム血症	Overall	1(0.5)
	Mild	-
	Moderate	1(0.5)
	Severe	-
筋骨格系および結合組織障害	Overall	34(15.3)
	Mild	28(12.6)
	Moderate	6(2.7)
	Severe	-
関節痛	Overall	5(2.3)
	Mild	4(1.8)
	Moderate	1(0.5)
	Severe	-
背部痛	Overall	4(1.8)
	Mild	2(0.9)
	Moderate	2(0.9)
	Severe	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.2-1) Table 4.1.1.5

表 2.7.4.7-付録-21　有害事象の程度別発現頻度（OCT-002 試験）（29/50）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) 1 mg (N=222)
筋骨格系および結合組織障害（続き）		
変形性関節症	Overall	4(1.8)
	Mild	3(1.4)
	Moderate	1(0.5)
	Severe	-
筋骨格痛	Overall	3(1.4)
	Mild	3(1.4)
	Moderate	-
	Severe	-
四肢痛	Overall	3(1.4)
	Mild	3(1.4)
	Moderate	-
	Severe	-
筋痙縮	Overall	2(0.9)
	Mild	2(0.9)
	Moderate	-
	Severe	-
筋骨格硬直	Overall	2(0.9)
	Mild	2(0.9)
	Moderate	-
	Severe	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.2-1) Table 4.1.1.5

表 2.7.4.7-付録-21　有害事象の程度別発現頻度（OCT-002 試験）（30/50）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) 1 mg (N=222)
筋骨格系および結合組織障害（続き）		
頚部痛	Overall	2(0.9)
	Mild	2(0.9)
	Moderate	-
	Severe	-
変形性脊椎症	Overall	2(0.9)
	Mild	2(0.9)
	Moderate	-
	Severe	-
関節炎	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-
大腿骨寛骨臼インピンジメント	Overall	1(0.5)
	Mild	-
	Moderate	1(0.5)
	Severe	-
椎間板突出	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.2-1) Table 4.1.1.5

表 2.7.4.7-付録-21　有害事象の程度別発現頻度（OCT-002 試験）（31/50）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) 1 mg (N=222)
筋骨格系および結合組織障害（続き）		
関節腫脹	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-
四肢不快感	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-
腰部脊柱管狭窄症	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-
筋肉痛	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-
骨粗鬆症	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.2-1) Table 4.1.1.5

表 2.7.4.7-付録-21　有害事象の程度別発現頻度（OCT-002 試験）（32/50）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) 1 mg (N=222)
筋骨格系および結合組織障害（続き）		
横紋筋融解症	Overall	1(0.5)
	Mild	-
	Moderate	1(0.5)
	Severe	-
脊柱管狭窄症	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-
顎関節症候群	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-
腱炎	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-
弾発指	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.2-1) Table 4.1.1.5

表 2.7.4.7-付録-21　有害事象の程度別発現頻度（OCT-002 試験）（33/50）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) 1 mg (N=222)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	Overall	6(2.7)
	Mild	2(0.9)
	Moderate	4(1.8)
	Severe	-
大腸腺腫	Overall	2(0.9)
	Mild	-
	Moderate	2(0.9)
	Severe	-
膵癌	Overall	1(0.5)
	Mild	-
	Moderate	1(0.5)
	Severe	-
脂漏性角化症	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-
皮膚乳頭腫	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-
甲状腺癌	Overall	1(0.5)
	Mild	-
	Moderate	1(0.5)
	Severe	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.2-1) Table 4.1.1.5

表 2.7.4.7-付録-21　有害事象の程度別発現頻度（OCT-002 試験）（34/50）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) 1 mg (N=222)
神経系障害	Overall	54(24.3)
	Mild	30(13.5)
	Moderate	23(10.4)
	Severe	1(0.5)
ジスキネジア	Overall	24(10.8)
	Mild	17(7.7)
	Moderate	7(3.2)
	Severe	-
頭痛	Overall	10(4.5)
	Mild	8(3.6)
	Moderate	2(0.9)
	Severe	-
失神	Overall	4(1.8)
	Mild	-
	Moderate	4(1.8)
	Severe	-
パーキンソニズム	Overall	3(1.4)
	Mild	-
	Moderate	3(1.4)
	Severe	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.2-1) Table 4.1.1.5

表 2.7.4.7-付録-21　有害事象の程度別発現頻度（OCT-002 試験）（35/50）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) 1 mg (N=222)
神経系障害（続き）		
傾眠	Overall	3(1.4)
	Mild	2(0.9)
	Moderate	1(0.5)
	Severe	-
異常感覚	Overall	2(0.9)
	Mild	2(0.9)
	Moderate	-
	Severe	-
意識消失	Overall	2(0.9)
	Mild	1(0.5)
	Moderate	1(0.5)
	Severe	-
パーキンソン病	Overall	2(0.9)
	Mild	1(0.5)
	Moderate	1(0.5)
	Severe	-
咬舌	Overall	2(0.9)
	Mild	2(0.9)
	Moderate	-
	Severe	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.2-1) Table 4.1.1.5

表 2.7.4.7-付録-21　有害事象の程度別発現頻度（OCT-002 試験）（36/50）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) 1 mg (N=222)
神経系障害（続き）		
意識変容状態	Overall	1(0.5)
	Mild	-
	Moderate	1(0.5)
	Severe	-
自律神経ニューロパチー	Overall	1(0.5)
	Mild	-
	Moderate	1(0.5)
	Severe	-
認知障害	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-
浮動性めまい	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-
ジストニア	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.2-1) Table 4.1.1.5

表 2.7.4.7-付録-21　有害事象の程度別発現頻度（OCT-002 試験）（37/50）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) 1 mg (N=222)
神経系障害（続き）		
感覚鈍麻	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-
感覚異常性大腿神経痛	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-
片頭痛	Overall	1(0.5)
	Mild	-
	Moderate	1(0.5)
	Severe	-
ミオクローヌス	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-
パーキンソン歩行	Overall	1(0.5)
	Mild	-
	Moderate	-
	Severe	1(0.5)

有害事象名：MedDRA/J ver[redacted]. Statistical Analysis Report (5.3.5.2-1) Table 4.1.1.5

表 2.7.4.7-付録-21　有害事象の程度別発現頻度（OCT-002 試験）（38/50）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) 1 mg (N=222)
神経系障害（続き）		
橈骨神経麻痺	Overall	1(0.5)
	Mild	-
	Moderate	1(0.5)
	Severe	-
安静時振戦	Overall	1(0.5)
	Mild	-
	Moderate	1(0.5)
	Severe	-
精神障害	Overall	22(9.9)
	Mild	14(6.3)
	Moderate	7(3.2)
	Severe	1(0.5)
幻覚	Overall	7(3.2)
	Mild	5(2.3)
	Moderate	1(0.5)
	Severe	1(0.5)
幻視	Overall	3(1.4)
	Mild	2(0.9)
	Moderate	1(0.5)
	Severe	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.2-1) Table 4.1.1.5

表 2.7.4.7-付録-21　有害事象の程度別発現頻度（OCT-002 試験）（39/50）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) 1 mg (N=222)
精神障害（続き）		
異常行動	Overall	2(0.9)
	Mild	-
	Moderate	2(0.9)
	Severe	-
譫妄	Overall	2(0.9)
	Mild	1(0.5)
	Moderate	1(0.5)
	Severe	-
不安	Overall	1(0.5)
	Mild	-
	Moderate	1(0.5)
	Severe	-
失見当識	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-
頭を激しくぶっつける	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.2-1) Table 4.1.1.5

表 2.7.4.7-付録-21　有害事象の程度別発現頻度（OCT-002 試験）（40/50）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) 1 mg (N=222)
精神障害（続き）		
軽躁	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-
錯覚	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-
不眠症	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-
パニック障害	Overall	1(0.5)
	Mild	-
	Moderate	1(0.5)
	Severe	-
精神症状	Overall	1(0.5)
	Mild	-
	Moderate	1(0.5)
	Severe	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.2-1) Table 4.1.1.5

表 2.7.4.7-付録-21　有害事象の程度別発現頻度（OCT-002 試験）（41/50）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) 1 mg (N=222)
精神障害（続き）		
睡眠発作	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-
腎および尿路障害	Overall	6(2.7)
	Mild	3(1.4)
	Moderate	3(1.4)
	Severe	-
緊張性膀胱	Overall	4(1.8)
	Mild	3(1.4)
	Moderate	1(0.5)
	Severe	-
頻尿	Overall	1(0.5)
	Mild	-
	Moderate	1(0.5)
	Severe	-
切迫性尿失禁	Overall	1(0.5)
	Mild	-
	Moderate	1(0.5)
	Severe	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.2-1) Table 4.1.1.5

表 2.7.4.7-付録-21　有害事象の程度別発現頻度（OCT-002 試験）（42/50）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) 1 mg (N=222)
腎および尿路障害（続き）		
尿失禁	Overall	1(0.5)
	Mild	-
	Moderate	1(0.5)
	Severe	-
生殖系および乳房障害	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-
良性前立腺肥大症	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-
呼吸器、胸郭および縦隔障害	Overall	11(5.0)
	Mild	10(4.5)
	Moderate	1(0.5)
	Severe	-
咳嗽	Overall	3(1.4)
	Mild	3(1.4)
	Moderate	-
	Severe	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.2-1) Table 4.1.1.5

表 2.7.4.7-付録-21　有害事象の程度別発現頻度（OCT-002 試験）（43/50）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) 1 mg (N=222)
呼吸器、胸郭および縦隔障害（続き）		
呼吸困難	Overall	3(1.4)
	Mild	3(1.4)
	Moderate	-
	Severe	-
上気道の炎症	Overall	3(1.4)
	Mild	3(1.4)
	Moderate	-
	Severe	-
喘息	Overall	1(0.5)
	Mild	-
	Moderate	1(0.5)
	Severe	-
カタル	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-
鼻出血	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.2-1) Table 4.1.1.5

表 2.7.4.7-付録-21　有害事象の程度別発現頻度（OCT-002 試験）（44/50）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) 1 mg (N=222)
呼吸器、胸郭および縦隔障害（続き）		
過換気	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-
口腔咽頭痛	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-
アレルギー性鼻炎	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-
皮膚および皮下組織障害	Overall	35(15.8)
	Mild	33(14.9)
	Moderate	2(0.9)
	Severe	-
湿疹	Overall	9(4.1)
	Mild	9(4.1)
	Moderate	-
	Severe	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.2-1) Table 4.1.1.5

表 2.7.4.7-付録-21　有害事象の程度別発現頻度（OCT-002 試験）（45/50）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) 1 mg (N=222)
皮膚および皮下組織障害（続き）		
褥瘡性潰瘍	Overall	4(1.8)
	Mild	3(1.4)
	Moderate	1(0.5)
	Severe	-
そう痒症	Overall	4(1.8)
	Mild	4(1.8)
	Moderate	-
	Severe	-
接触性皮膚炎	Overall	3(1.4)
	Mild	3(1.4)
	Moderate	-
	Severe	-
皮脂欠乏性湿疹	Overall	3(1.4)
	Mild	3(1.4)
	Moderate	-
	Severe	-
紅斑	Overall	2(0.9)
	Mild	2(0.9)
	Moderate	-
	Severe	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.2-1) Table 4.1.1.5

表 2.7.4.7-付録-21　有害事象の程度別発現頻度（OCT-002 試験）（46/50）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) 1 mg (N=222)
皮膚および皮下組織障害（続き）		
過角化	Overall	2(0.9)
	Mild	2(0.9)
	Moderate	-
	Severe	-
円形脱毛症	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-
皮膚炎	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-
乾癬様皮膚炎	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-
薬疹	Overall	1(0.5)
	Mild	-
	Moderate	1(0.5)
	Severe	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.2-1) Table 4.1.1.5

表 2.7.4.7-付録-21　有害事象の程度別発現頻度（OCT-002 試験）（47/50）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) 1 mg (N=222)
皮膚および皮下組織障害（続き）		
多汗症	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-
嵌入爪	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-
神経皮膚炎	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-
紫斑	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-
全身性皮疹	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.2-1) Table 4.1.1.5

表 2.7.4.7-付録-21　有害事象の程度別発現頻度（OCT-002 試験）（48/50）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) 1 mg (N=222)
皮膚および皮下組織障害（続き）		
脂漏性皮膚炎	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-
皮膚剥脱	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-
うっ滞性皮膚炎	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-
中毒性皮疹	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-
蕁麻疹	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-

有害事象名：MedDRA/J ver[redacted]. Statistical Analysis Report (5.3.5.2-1) Table 4.1.1.5

表 2.7.4.7-付録-21　有害事象の程度別発現頻度（OCT-002 試験）（49/50）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) 1 mg (N=222)
皮膚および皮下組織障害（続き）		
黄色腫	Overall	1(0.5)
	Mild	1(0.5)
	Moderate	-
	Severe	-
血管障害	Overall	22(9.9)
	Mild	14(6.3)
	Moderate	7(3.2)
	Severe	1(0.5)
起立性低血圧	Overall	12(5.4)
	Mild	8(3.6)
	Moderate	4(1.8)
	Severe	-
高血圧	Overall	7(3.2)
	Mild	4(1.8)
	Moderate	3(1.4)
	Severe	-
内出血	Overall	3(1.4)
	Mild	3(1.4)
	Moderate	-
	Severe	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.2-1) Table 4.1.1.5

表 2.7.4.7-付録-21　有害事象の程度別発現頻度（OCT-002 試験）（50/50）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) 1 mg (N=222)
血管障害（続き）		
低血圧	Overall	2(0.9)
	Mild	2(0.9)
	Moderate	-
	Severe	-
大動脈解離	Overall	1(0.5)
	Mild	-
	Moderate	-
	Severe	1(0.5)

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.2-1) Table 4.1.1.5

表 2.7.4.7-付録-22　治験薬との因果関係が「関連あり」の有害事象の程度別発現頻度（CCT-001 試験）（1/21）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=126)	 1 mg (N=117)
Subjects with Any TEAEs	Overall	35(27.8)	46(39.3)
	Mild	27(21.4)	40(34.2)
	Moderate	5(4.0)	6(5.1)
	Severe	3(2.4)	-
心臓障害	Overall	1(0.8)	2(1.7)
	Mild	-	2(1.7)
	Moderate	1(0.8)	-
	Severe	-	-
期外収縮	Overall	-	1(0.9)
	Mild	-	1(0.9)
	Moderate	-	-
	Severe	-	-
心筋梗塞	Overall	1(0.8)	-
	Mild	-	-
	Moderate	1(0.8)	-
	Severe	-	-
動悸	Overall	-	1(0.9)
	Mild	-	1(0.9)
	Moderate	-	-
	Severe	-	-
耳および迷路障害	Overall	2(1.6)	2(1.7)
	Mild	2(1.6)	2(1.7)
	Moderate	-	-
	Severe	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.1-6) Table 4.1.1.6

表 2.7.4.7-付録-22　治験薬との因果関係が「関連あり」の有害事象の程度別発現頻度（CCT-001 試験）（2/21）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=126)	 1 mg (N=117)
耳および迷路障害（続き）			
回転性めまい	Overall	2(1.6)	-
	Mild	2(1.6)	-
	Moderate	-	-
	Severe	-	-
聴力低下	Overall	-	1(0.9)
	Mild	-	1(0.9)
	Moderate	-	-
	Severe	-	-
耳鳴	Overall	-	1(0.9)
	Mild	-	1(0.9)
	Moderate	-	-
	Severe	-	-
眼障害	Overall	1(0.8)	1(0.9)
	Mild	1(0.8)	1(0.9)
	Moderate	-	-
	Severe	-	-
結膜出血	Overall	1(0.8)	-
	Mild	1(0.8)	-
	Moderate	-	-
	Severe	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.1-6) Table 4.1.1.6

表 2.7.4.7-付録-22　治験薬との因果関係が「関連あり」の有害事象の程度別発現頻度（CCT-001 試験）（3/21）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=126)	 1 mg (N=117)
眼障害（続き）			
硝子体浮遊物	Overall	-	1(0.9)
	Mild	-	1(0.9)
	Moderate	-	-
	Severe	-	-
胃腸障害	Overall	9(7.1)	15(12.8)
	Mild	8(6.3)	14(12.0)
	Moderate	1(0.8)	1(0.9)
	Severe	-	-
便秘	Overall	2(1.6)	1(0.9)
	Mild	2(1.6)	1(0.9)
	Moderate	-	-
	Severe	-	-
胃潰瘍	Overall	1(0.8)	2(1.7)
	Mild	-	1(0.9)
	Moderate	1(0.8)	1(0.9)
	Severe	-	-
下腹部痛	Overall	1(0.8)	1(0.9)
	Mild	1(0.8)	1(0.9)
	Moderate	-	-
	Severe	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.1-6) Table 4.1.1.6

表 2.7.4.7-付録-22　治験薬との因果関係が「関連あり」の有害事象の程度別発現頻度（CCT-001 試験）（4/21）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=126)	 1 mg (N=117)
胃腸障害（続き）			
悪心	Overall	-	2(1.7)
	Mild	-	2(1.7)
	Moderate	-	-
	Severe	-	-
口内炎	Overall	-	2(1.7)
	Mild	-	2(1.7)
	Moderate	-	-
	Severe	-	-
腹痛	Overall	-	1(0.9)
	Mild	-	1(0.9)
	Moderate	-	-
	Severe	-	-
上腹部痛	Overall	-	1(0.9)
	Mild	-	1(0.9)
	Moderate	-	-
	Severe	-	-
急性腹症	Overall	-	1(0.9)
	Mild	-	1(0.9)
	Moderate	-	-
	Severe	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.1-6) Table 4.1.1.6

表 2.7.4.7-付録-22　治験薬との因果関係が「関連あり」の有害事象の程度別発現頻度（CCT-001 試験）（5/21）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=126)	 1 mg (N=117)
胃腸障害（続き）			
アフタ性潰瘍	Overall	1(0.8)	-
	Mild	1(0.8)	-
	Moderate	-	-
	Severe	-	-
慢性胃炎	Overall	1(0.8)	-
	Mild	1(0.8)	-
	Moderate	-	-
	Severe	-	-
虚血性大腸炎	Overall	1(0.8)	-
	Mild	1(0.8)	-
	Moderate	-	-
	Severe	-	-
齲歯	Overall	-	1(0.9)
	Mild	-	1(0.9)
	Moderate	-	-
	Severe	-	-
下痢	Overall	-	1(0.9)
	Mild	-	1(0.9)
	Moderate	-	-
	Severe	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.1-6) Table 4.1.1.6

表 2.7.4.7-付録-22　治験薬との因果関係が「関連あり」の有害事象の程度別発現頻度（CCT-001 試験）（6/21）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=126)	 1 mg (N=117)
胃腸障害（続き）			
胃炎	Overall	1(0.8)	-
	Mild	1(0.8)	-
	Moderate	-	-
	Severe	-	-
びらん性胃炎	Overall	1(0.8)	-
	Mild	1(0.8)	-
	Moderate	-	-
	Severe	-	-
胃食道逆流性疾患	Overall	1(0.8)	-
	Mild	1(0.8)	-
	Moderate	-	-
	Severe	-	-
大腸ポリープ	Overall	-	1(0.9)
	Mild	-	1(0.9)
	Moderate	-	-
	Severe	-	-
歯周病	Overall	-	1(0.9)
	Mild	-	1(0.9)
	Moderate	-	-
	Severe	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.1-6) Table 4.1.1.6

表 2.7.4.7-付録-22　治験薬との因果関係が「関連あり」の有害事象の程度別発現頻度（CCT-001 試験）（7/21）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=126)	 1 mg (N=117)
一般・全身障害および投与部位の状態	Overall	1(0.8)	1(0.9)
	Mild	1(0.8)	1(0.9)
	Moderate	-	-
	Severe	-	-
末梢性浮腫	Overall	-	1(0.9)
	Mild	-	1(0.9)
	Moderate	-	-
	Severe	-	-
口渇	Overall	1(0.8)	-
	Mild	1(0.8)	-
	Moderate	-	-
	Severe	-	-
免疫系障害	Overall	-	1(0.9)
	Mild	-	1(0.9)
	Moderate	-	-
	Severe	-	-
季節性アレルギー	Overall	-	1(0.9)
	Mild	-	1(0.9)
	Moderate	-	-
	Severe	-	-
感染症および寄生虫症	Overall	5(4.0)	12(10.3)
	Mild	4(3.2)	10(8.5)
	Moderate	1(0.8)	2(1.7)
	Severe	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.1-6) Table 4.1.1.6

表 2.7.4.7-付録-22　治験薬との因果関係が「関連あり」の有害事象の程度別発現頻度（CCT-001 試験）（8/21）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=126)	 1 mg (N=117)
感染症および寄生虫症（続き）			
鼻咽頭炎	Overall	3(2.4)	5(4.3)
	Mild	3(2.4)	5(4.3)
	Moderate	-	-
	Severe	-	-
気管支炎	Overall	-	1(0.9)
	Mild	-	1(0.9)
	Moderate	-	-
	Severe	-	-
結膜炎	Overall	1(0.8)	-
	Mild	1(0.8)	-
	Moderate	-	-
	Severe	-	-
胃腸炎	Overall	-	1(0.9)
	Mild	-	-
	Moderate	-	1(0.9)
	Severe	-	-
ウイルス性胃腸炎	Overall	-	1(0.9)
	Mild	-	-
	Moderate	-	1(0.9)
	Severe	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.1-6) Table 4.1.1.6

表 2.7.4.7-付録-22　治験薬との因果関係が「関連あり」の有害事象の程度別発現頻度（CCT-001 試験）（9/21）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=126)	 1 mg (N=117)
感染症および寄生虫症（続き）			
帯状疱疹	Overall	1(0.8)	-
	Mild	-	-
	Moderate	1(0.8)	-
	Severe	-	-
口腔ヘルペス	Overall	-	1(0.9)
	Mild	-	1(0.9)
	Moderate	-	-
	Severe	-	-
咽頭炎	Overall	-	1(0.9)
	Mild	-	1(0.9)
	Moderate	-	-
	Severe	-	-
歯髄炎	Overall	1(0.8)	-
	Mild	1(0.8)	-
	Moderate	-	-
	Severe	-	-
副鼻腔炎	Overall	-	1(0.9)
	Mild	-	1(0.9)
	Moderate	-	-
	Severe	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.1-6) Table 4.1.1.6

表 2.7.4.7-付録-22　治験薬との因果関係が「関連あり」の有害事象の程度別発現頻度（CCT-001 試験）（10/21）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=126)	 1 mg (N=117)
感染症および寄生虫症（続き）			
腟感染	Overall	-	1(0.9)
	Mild	-	1(0.9)
	Moderate	-	-
	Severe	-	-
傷害、中毒および処置合併症	Overall	3(2.4)	-
	Mild	3(2.4)	-
	Moderate	-	-
	Severe	-	-
転倒	Overall	2(1.6)	-
	Mild	2(1.6)	-
	Moderate	-	-
	Severe	-	-
挫傷	Overall	1(0.8)	-
	Mild	1(0.8)	-
	Moderate	-	-
	Severe	-	-
靭帯捻挫	Overall	1(0.8)	-
	Mild	1(0.8)	-
	Moderate	-	-
	Severe	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.1-6) Table 4.1.1.6

表 2.7.4.7-付録-22　治験薬との因果関係が「関連あり」の有害事象の程度別発現頻度（CCT-001 試験）（11/21）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=126)	 1 mg (N=117)
臨床検査	Overall	4(3.2)	3(2.6)
	Mild	4(3.2)	2(1.7)
	Moderate	-	1(0.9)
	Severe	-	-
血中クレアチンホスホキナーゼ増加	Overall	2(1.6)	-
	Mild	2(1.6)	-
	Moderate	-	-
	Severe	-	-
血中アルカリホスファターゼ増加	Overall	1(0.8)	-
	Mild	1(0.8)	-
	Moderate	-	-
	Severe	-	-
血圧上昇	Overall	-	1(0.9)
	Mild	-	1(0.9)
	Moderate	-	-
	Severe	-	-
心電図ＱＴ延長	Overall	-	1(0.9)
	Mild	-	-
	Moderate	-	1(0.9)
	Severe	-	-
γ－グルタミルトランスフェラーゼ増加	Overall	1(0.8)	-
	Mild	1(0.8)	-
	Moderate	-	-
	Severe	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.1-6) Table 4.1.1.6

表 2.7.4.7-付録-22　治験薬との因果関係が「関連あり」の有害事象の程度別発現頻度（CCT-001 試験）（12/21）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=126)	 1 mg (N=117)
臨床検査（続き）			
肝酵素上昇	Overall	1(0.8)	-
	Mild	1(0.8)	-
	Moderate	-	-
	Severe	-	-
肝機能検査異常	Overall	-	1(0.9)
	Mild	-	1(0.9)
	Moderate	-	-
	Severe	-	-
筋骨格系および結合組織障害	Overall	3(2.4)	5(4.3)
	Mild	3(2.4)	4(3.4)
	Moderate	-	1(0.9)
	Severe	-	-
背部痛	Overall	2(1.6)	1(0.9)
	Mild	2(1.6)	1(0.9)
	Moderate	-	-
	Severe	-	-
関節痛	Overall	-	2(1.7)
	Mild	-	1(0.9)
	Moderate	-	1(0.9)
	Severe	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.1-6) Table 4.1.1.6

表 2.7.4.7-付録-22　治験薬との因果関係が「関連あり」の有害事象の程度別発現頻度（CCT-001 試験）（13/21）

System Organ Class Preferred Term	Intensity	Number of Subjects (%) Placebo (N=126)	 1 mg (N=117)
筋骨格系および結合組織障害（続き）			
指変形	Overall	-	1(0.9)
	Mild	-	1(0.9)
	Moderate	-	-
	Severe	-	-
筋骨格硬直	Overall	-	1(0.9)
	Mild	-	1(0.9)
	Moderate	-	-
	Severe	-	-
関節周囲炎	Overall	1(0.8)	-
	Mild	1(0.8)	-
	Moderate	-	-
	Severe	-	-
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	Overall	-	1(0.9)
	Mild	-	1(0.9)
	Moderate	-	-
	Severe	-	-
脂漏性角化症	Overall	-	1(0.9)
	Mild	-	1(0.9)
	Moderate	-	-
	Severe	-	-

有害事象名：MedDRA/J ver[redacted]、Statistical Analysis Report (5.3.5.1-6) Table 4.1.1.6