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This English version is intended to be a reference material to provide convenience for users. In the event of inconsistency between the Japanese original and this

English translation, the former shall prevail.

Revision of Precautions

Canagliflozin hydrate

May 9, 2019

Therapeutic category

Antidiabetic agents

Non-proprietary name

Canagliflozin hydrate

Safety measure

Precautions should be revised in the package insert.

Pharmaceuticals and Medical Devices Agency

3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan E-mail: <u>safety.info@pmda.go.jp</u> Revision in line with the Instructions for Package Inserts of Prescription Drugs, PAB Notification No. 606 by the Director General ofPharmaceutical Affairs Bureau, MHW, dated April 25, 1997 (Old instructions):Revised language is underlined.

Current	Revision
Important Precautions	Important Precautions
Urinary tract infection may occur, which may lead to serious	Urinary tract infection and genital infection may occur, which may
infections such as pyelonephritis and sepsis. Genital infection such	lead to serious infections such as pyelonephritis, necrotising fasciitis
as vaginal candidiasis may also occur. Patients should be carefully	of the external genitalia and perineum (Fournier's gangrene), and
monitored for urinary tract infection and genital infection. If such	sepsis. Patients should be carefully monitored for urinary tract
infections occur, appropriate measures should be taken, and	infection and genital infection. If such infections occur, appropriate
measures such as temporary discontinuation of this drug should be	measures should be taken, and measures such as temporary
considered based on the patient's condition. Symptoms and	discontinuation of this drug should be considered based on the
management of urinary tract infection and genital infection should	patient's condition. Symptoms and management of urinary tract
be explained to patients.	infection and genital infection should be explained to patients.
Adverse Reactions	Adverse Reactions
Clinically Significant Adverse Reactions	Clinically Significant Adverse Reactions
Pyelonephritis, sepsis:	Pyelonephritis, necrotising fasciitis of the external genitalia and
Pyelonephritis may occur, which may lead to sepsis (including	<u>perineum (Fournier's gangrene), </u> sepsis:
septic shock). Patients should be carefully monitored. If any	Pyelonephritis, necrotising fasciitis of the external genitalia and
abnormalities are observed, administration of this drug should be	perineum (Fournier's gangrene) may occur, which may lead to
discontinued, and appropriate measures should be taken.	sepsis (including septic shock). Patients should be carefully
	monitored. If any abnormalities are observed, administration of this
	drug should be discontinued, and appropriate measures should be
	taken.

Pharmaceuticals and Medical Devices Agency

3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan E-mail: <u>safety.info@pmda.go.jp</u> Revision in line with the Instructions for Package Inserts of Prescription Drugs, etc. PSEHB Notification No. 0608-1 by the Director of Pharmaceutical Safety and Environmental Health Bureau, MHLW, dated June 8, 2017(New instructions): Revised language is underlined.

Current	Revision
8. IMPORTANT PRECAUTIONS	8. IMPORTANT PRECAUTIONS
Urinary tract infection may occur, which may lead to serious	Urinary tract infection and genital infection may occur, which may
infections such as pyelonephritis and sepsis. Genital infection such	lead to serious infections such as pyelonephritis, necrotising
as vaginal candidiasis may also occur. Patients should be carefully	fasciitis of the external genitalia and perineum (Fournier's
monitored for urinary tract infection and genital infection. If such	gangrene), and sepsis. Patients should be carefully monitored for
infections occur, appropriate measures should be taken, and	urinary tract infection and genital infection. If such infections occur,
measures such as temporary discontinuation of this drug should be	appropriate measures should be taken, and measures such as
considered based on the patient's condition. Symptoms and	temporary discontinuation of this drug should be considered based
management of urinary tract infection and genital infection should	on the patient's condition. Symptoms and management of urinary
be explained to patients.	tract infection and genital infection should be explained to patients.
11. ADVERSE REACTIONS	11. ADVERSE REACTIONS
11.1 Clinically Significant Adverse Reactions	11.1 Clinically Significant Adverse Reactions
Pyelonephritis, sepsis	Pyelonephritis, necrotising fasciitis of the external genitalia and
Pyelonephritis may occur, which may lead to sepsis (including	<u>perineum (Fournier's gangrene),</u> sepsis
septic shock).	Pyelonephritis, necrotising fasciitis of the external genitalia and
	perineum (Fournier's gangrene) may occur, which may lead to
	sepsis (including septic shock).

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