

Summary of Investigation Results

Kakkonto (For Ethical Use)

Non-proprietary name	Non-proprietary name	Brand name (marketing authorization holder)
Brand name	Kakkonto	See Attachment.
Japanese market launch	See Attachment.	
Indications	See Attachment.	
Summary of revisions	"Erythema multiforme" should be added to the 11.1 Clinically Significant Adverse Reactions section in 11. ADVERSE REACTIONS.	
Investigation results and background of the revision	Cases involving erythema multiforme were evaluated. Cases in which a causal relationship between kakkonto and erythema multiforme was reasonably possible have been reported. As a result of consultation with expert advisors regarding the causality assessment of the cases and the necessity of revision of PRECAUTIONS, the MHLW/PMDA concluded that revision of PRECAUTIONS was necessary.	
Reference: Number of cases* involving "erythema multiforme" reported in Japan	A total of 6 cases have been reported to date (including 4 cases in which a causal relationship between the drug and the event was reasonably possible). No deaths have been reported to date.	

*: Among cases involving use of ethical and OTC drugs collected in the PMDA's safety database for drugs, cases of events corresponding to erythema multiforme major (EM major) reported with PTs "Erythema multiforme" and "Drug eruption"

The expert advisors present at the Expert Discussion regarding the current investigation were nominated based on their conflict of interest declarations concerning the relevant products, pursuant to the "Rules for Convening Expert Discussions, etc.", by the Pharmaceuticals and Medical Devices Agency" (PMDA Administrative Rule No. 20-8, dated December 25, 2008).

(Attachment)

	Brand name (Marketing authorization holder)	Indications	Japanese market launch
1	TSUMURA Kakkonto Extract Granules for Ethical Use (TSUMURA & CO.)	The following symptoms in patients with a comparatively strong constitution who have headache, fever, rigor, and shoulder stiffness without spontaneous sweating: Common cold, head cold, initial stage of febrile diseases, inflammatory diseases (conjunctivitis, keratitis, otitis media, tonsillitis, mastitis, lymph gland inflammation), shoulder stiffness, nerve pain in the upper body, and hives	October 1986
2	Kracie Kakkonto Extract Fine Granules (Kracie, Ltd.)	Common cold, head cold, headache, shoulder stiffness, muscle pain, and hand/shoulder pain	October 1986
3	Kotaro Kakkonto Extract Fine Granules (Kotaro pharmaceutical Co., Ltd)	Conditions of headache, fever, chills without spontaneous sweating, stiffness of the regions such as nape, shoulder, and back, or diarrhea Common cold, head cold, sinusitis, tonsillitis, conjunctivitis, mastitis, eczema, urticaria, shoulder stiffness, neuralgia, and migraine.	October 1986
4	SANWA Kakkonto Extract Fine Granules (Sanwa Shoyaku Co Ltd.)	The following symptoms in patients with a comparatively strong constitution who have headache, fever, chills, and shoulder and back stiffness without spontaneous sweating: Common cold, head cold, tonsillitis, otitis media, sinusitis, conjunctivitis, mastitis, shoulder stiffness, and brachial neuralgia.	November 1986
5	JUNKOU Kakkonto FC Extract Fine Granules for Ethical Use (Kowa Yakutsu Y.K.)	Common cold, head cold, headache, shoulder stiffness, muscle pain, and hand/shoulder pain	October 1986
6	TOYO kakkonto extract fine granules (Toyo-yakuko Co., Ltd)	Common cold, head cold, headache, shoulder stiffness, muscle pain, and hand/shoulder pain	December 1986
7	OHSUGI Kakkonto Extract Granules G (OHSUGI Pharmaceutical Co., Ltd.)	Common cold, head cold, headache, shoulder stiffness, muscle pain, and hand/shoulder pain	October 1986
8	JPS Kakkonto Extract Granules for Ethical Use (JPS Pharmaceutical CO., LTD.)	Common cold, head cold, headache, shoulder stiffness, muscle pain, and hand/shoulder pain	October 1987
9	Taikoseido Kakkonto Extract Granules (Taikoseido Pharmaceutical Co., Ltd.)	Common cold, head cold, headache, shoulder stiffness, muscle pain, and hand/shoulder pain	November 1986
10	Honzo kakkonto extract granules-M (Honzo Pharmaceutical Co., Ltd.)	Common cold, head cold, headache, shoulder stiffness, muscle pain, and hand/shoulder pain	October 1986
11	OHSUGI Kakkonto Extract T Tablets (OHSUGI Pharmaceutical Co., Ltd.)	Common cold, head cold, headache, shoulder stiffness, muscle pain, and hand/shoulder pain	October 1987

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

	Brand name (Marketing authorization holder)	Indications	Japanese market launch
12	Kracie Kakkonto Extract Tablets T (Ominedo Pharmaceutical Industry Co., Ltd.)	Common cold, head cold, headache, shoulder stiffness, muscle pain, and hand/shoulder pain	October 1986