August 25, 2026
Pharmaceuticals and Medical Devices Agency, Japan

Summary of Investigation Results

Preparations containing kakkonto (OTC drugs)

Non-proprietary name Brand name	Non-proprietary name	Brand name (marketing authorization holder)
	Preparations containing Kakkonto	Tsumura-Kampo Kakkonto Extract Granules A (TSUMURA & CO.) PRECOL ace granulated powder (TAMURA PHARMACEUTICAL CO., LTD.) Other OTC drugs
Japanese market launch	-	
Indications	○ Tsumura-Kampo Kakkonto Extract Granules A The following symptoms in persons with moderate or higher physical strength: Initial stage of common cold (without spontaneous sweating), head cold, rhinitis, headache, shoulder stiffness, muscle pain, and hand/shoulder pain ○ PRECOL ace granulated powder Relief of cold symptoms (runny nose, stuffy nose, sneezing, sore throat, cough, phlegm, chills, fever, headache, joint pain, muscle pain)	
Summary of revisions	"Erythema multiforme" should be added to the Consultation section.	
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).