



Summary of Investigation Results

Iopamidol

March 30, 2021

Non-proprietary name

Iopamidol

Branded name (Marketing authorization holder)

See Attachment

Indications

See Attachment

Summary of revisions

“Acute generalised exanthematous pustulosis” should be added to the “skin disorder” in the Clinically Significant Adverse Reactions section.

Investigation results and background of the revision

Cases of acute generalised exanthematous pustulosis have been reported in patients treated with Iopamidol in Japan. MHLW/PMDA in consultation with expert advisors concluded that revision of the package insert was necessary.

Number of cases and patient mortalities reported in Japan during the previous 3 fiscal years

A total of 4 cases involving acute generalised exanthematous pustulosis have been reported to date (including 3 cases for which a causal relationship between the drug and event was reasonably possible).

No patient mortalities have been reported to date.



Pharmaceuticals and Medical Devices Agency

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.

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).

Pharmaceuticals and Medical Devices Agency

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Attachment

Non-proprietary name	Branded name	Marketing authorization holder	Indications
lopamidol	lopamiron Inj. 150 (50 mL), 150 (200 mL), and the others	Bayer Yakuhin, Ltd, and the others	Arteriography by digital X-ray method, computer-assisted tomography, intravenous urography, retrograde urography
	lopamiron Inj. 300 (20 mL), 300 (50 mL), 300 (100 mL), and the others lopamiron Inj. Syringe 300 (50 mL), Syringe 300 (80 mL), Syringe 300 (100 mL), and the others		Cerebral angiography, aortography, selective angiography, extremities angiography, venography by digital X-ray method, arteriography by digital X-ray method, computer-assisted tomography, intravenous urography, retrograde urography
	lopamiron Inj. 370 (20 mL), 370 (50 mL), 370 (100 mL), and the others lopamiron Inj. Syringe 370 (50 mL), Syringe 370 (65 mL), Syringe 370 (80 mL), Syringe 370 (100 mL), and the others		Angiocardiography (including pulmonary arteriography), aortography, selective angiography, extremities angiography, venography by digital X-ray method, arteriography by digital X-ray method, computer-assisted tomography, intravenous urography

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