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Summary of Investigation Results

Ioversol

May 9, 2023

Non-proprietary name

Ioversol

Brand name (marketing authorization holder)

See attachment.

Japanese market launch

See attachment.

Indications

See attachment.

Summary of revisions

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

Investigation results and background of the revision

Cases involving acute generalised exanthematous pustulosis reported in Japan and overseas were evaluated. Cases for which a causal relationship between ioversol and acute generalised exanthematous pustulosis was reasonably possible have been reported in Japan and overseas. 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* and patient mortalities involving acute generalised exanthematous pustulosis reported in Japan and overseas

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A total of 2 cases have been reported in Japan to date (including 1 case for which a causal relationship between the drug and event was reasonably possible).
No patient mortalities have been reported in Japan to date.

A total of 17 cases have been reported overseas to date (including 3 cases for which a causal relationship between the drug and event was reasonably possible).
No patient mortalities have been reported overseas to date.

*Cases collected in the PMDA's database for adverse drug reactions, etc. reports

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

Brand name (marketing authorization holder)	Japanese market launch	Indications
Optiray 240 Injection Syringe 100 mL (Guerbet Japan KK)	June 1996	Computer-assisted tomography
Optiray 320 Injection Syringe 75 mL, 100 mL (Guerbet Japan KK)	June 1996	Cerebral angiography, aortography, selective angiography, extremities angiography, arteriography by digital X-ray method, venography by digital X-ray method, computer-assisted tomography, intravenous urography
Optiray 350 Injection Syringe 100 mL (Guerbet Japan KK)	July 2009	Angiocardiography, aortography, selective angiography, abdominal computer-assisted tomography
Optiray 350 Injection Syringe 135 mL (Guerbet Japan KK)	August 2017	Abdominal computer-assisted tomography
Optiray 320 Injection 20 mL, 50 mL, 100 mL (Guerbet Japan KK)	May 1992	Cerebral angiography, aortography, selective angiography, extremities angiography, arteriography by digital X-ray method, venography by digital X-ray method, computer-assisted tomography, intravenous urography
Optiray 350 Injection 20 mL, 50 mL, 100 mL (Guerbet Japan KK)	May 1992	Angiocardiography, aortography, selective angiography, abdominal computer-assisted tomography

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