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.

Summary of Investigation Results

Iodixanol

August 27, 2024

Non-proprietary name

Iodixanol

Brand name (marketing authorization holder)

Visipaque 270 Injection 20 mL, 50 mL, 100 mL, Visipaque 320 Injection 50 mL, 100 mL (GE Healthcare Pharma Co., Ltd.)

Japanese market launch

November 2000

Indications

<Visipaque 270 Injection>

Cerebral angiography, extremities angiography, retrograde urography, endoscopic retrograde cholangiopancreatography

<Visipaque 320 Injection>

Extremities angiography

Summary of revisions

“Acute generalised exanthematous pustulosis” 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 acute generalised exanthematous pustulosis were evaluated. Cases for which a causal relationship between iodixanol and acute generalised exanthematous pustulosis 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

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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

No cases have been reported in Japan to date.

A total of 30 cases have been reported overseas to date (including 4 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
† Among the cases with acute generalised exanthematous pustulosis (MedDRA PT), only those cases containing information related to the diagnostic criteria were retrieved.

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).

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