独立行政法人 医薬品医療機器総合機構
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.

Summary of Investigation Results

Iodixanol

May 20, 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

1. “Cardiac arrest” should be added to the language stating that emergency measures should be prepared prior to administration of this drug in 8. IMPORTANT PRECAUTIONS.
2. “Cardiac arrest” 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 cardiac arrest were evaluated. Cases of cardiac arrest have been reported in which a causal relationship with iodixanol was considered reasonably possible, and where

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 cardiac arrest was not clearly associated with shock, anaphylaxis, or ventricular fibrillation, which are already warned of in the electronic package insert. 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 cardiac arrest reported in Japan and overseas

No cases have been reported in Japan to date.

A total of 31 cases have been reported overseas to date (including 3 cases for which a causal relationship between the drug and the event was reasonably possible).
A total of 15 patient mortalities have been reported overseas to date (including 1 case for which a causal relationship between the drug and the death subsequent to the event was reasonably possible).

*Among the cases collected in the PMDA's database for adverse drug reactions, etc. reports that resulted in cardiac arrest, the following cases were excluded: Cases which developed shock or anaphylaxis, for which a precaution had been included in the electronic package insert; cases with complications/past history, etc. that were considered to be a risk factor of cardiac arrest.

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).