

This document is an English-translated version of an attachment of a notification for Revision of PRECAUTIONS issued by the Ministry of Health, Labour and Welfare.

This English version is intended to be a reference material to provide convenience for users.

In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

Revision of PRECAUTIONS

Iodixanol

May 20, 2025

Therapeutic category

X-ray contrast agents

Non-proprietary name

Iodixanol

Safety measure

PRECAUTIONS should be revised.

Revised language is underlined.

Current	Revision
<p>8. IMPORTANT PRECAUTIONS</p> <p><Common to all indications></p> <p>Hypersensitivity may occur regardless of dosage and dosing regimen. Serious adverse reactions such as shock caused by this drug is not necessarily due to iodine hypersensitivity, and no methods are currently available for predicting them. Therefore, emergency measures should be prepared prior to administration of this drug.</p> <p>11. ADVERSE REACTIONS</p> <p>11.1 Clinically Significant Adverse Reactions</p> <p><Common to all indications></p> <p>(N/A)</p>	<p>8. IMPORTANT PRECAUTIONS</p> <p><Common to all indications></p> <p>Hypersensitivity may occur regardless of dosage and dosing regimen. Serious adverse reactions such as shock <u>and cardiac arrest</u> caused by this drug is not necessarily due to iodine hypersensitivity, and no methods are currently available for predicting them. Therefore, emergency measures should be prepared prior to administration of this drug.</p> <p>11. ADVERSE REACTIONS</p> <p>11.1 Clinically Significant Adverse Reactions</p> <p><Common to all indications></p> <p><u>Cardiac arrest</u></p>

N/A: Not Applicable. No corresponding language is included in the current PRECAUTIONS.