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Translated by
Pharmaceuticals and Medical Devices Agency



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

Iopamidol, iohexol

July 20, 2022

Therapeutic category

X-ray contrast agents

Non-proprietary name

Iopamidol, Iohexol

Safety measure

Precautions should be revised.

Pharmaceuticals and Medical Devices Agency

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Revision in line with the Instructions for Package Inserts of Prescription Drugs, PAB Notification No. 606 by the Director General of Pharmaceutical Affairs Bureau, MHW, dated April 25, 1997 (Old instructions): Revised language is underlined.

Current	Revision
Adverse Reactions Clinically Significant Adverse Reactions (N/A)	Adverse Reactions Clinically Significant Adverse Reactions <u>Acute coronary syndrome accompanying allergic reaction:</u> <u>Acute coronary syndrome accompanying allergic reaction may occur. Patients should be carefully monitored, and appropriate measures should be taken as necessary.</u>

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

Revision in line with the Instructions for Electronic Package Inserts of Prescription Drugs, etc. PSEHB Notification No. 0611-1 by the Director of Pharmaceutical Safety and Environmental Health Bureau, MHLW, dated June 11, 2021 (New instructions): Revised language is underlined.

Current	Revision
11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions <Common to all indications> (N/A)	11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions <Common to all indications> <u>Acute coronary syndrome accompanying allergic reaction</u>

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

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