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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

March 30, 2021

Therapeutic category

X-ray contrast agents

Non-proprietary name

Iopamidol

Safety measure

Precautions should be revised in the package insert.

Pharmaceuticals and Medical Devices Agency

3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan
E-mail: safety.info@pmda.go.jp

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
<p>Adverse Reactions</p> <p>Clinically Significant Adverse Reactions</p> <p>Skin disorder:</p> <p>Oculomucocutaneous syndrome (Stevens-Johnson syndrome) may occur. Patients should be carefully monitored, and appropriate measures should be taken if symptoms such as pyrexia, erythema, pruritus, ocular hyperaemia, or stomatitis are observed.</p>	<p>Adverse Reactions</p> <p>Clinically Significant Adverse Reactions</p> <p>Skin disorder:</p> <p>Oculomucocutaneous syndrome (Stevens-Johnson syndrome) <u>and acute generalised exanthematous pustulosis</u> may occur. Patients should be carefully monitored, and appropriate measures should be taken if symptoms such as pyrexia, erythema, <u>small pustules</u>, pruritus, ocular hyperaemia, or stomatitis are observed.</p>

Revision in line with the Instructions for Package Inserts of Prescription Drugs, etc. PSEHB Notification No. 0608-1 by the Director of Pharmaceutical Safety and Environmental Health Bureau, MHLW, dated June 8, 2017 (New instructions): Revised language is underlined.

Current	Revision
<p>11. ADVERSE REACTIONS</p> <p>11.1 Clinically Significant Adverse Reactions</p> <p><Common to all indications></p> <p>Skin disorder</p> <p>Oculomucocutaneous syndrome (Stevens-Johnson syndrome) may occur. Patients should be carefully monitored, and appropriate measures should be taken if symptoms such as pyrexia, erythema, pruritus, ocular hyperaemia, or stomatitis are observed.</p>	<p>11. ADVERSE REACTIONS</p> <p>11.1 Clinically Significant Adverse Reactions</p> <p><Common to all indications></p> <p>Skin disorder</p> <p>Oculomucocutaneous syndrome (Stevens-Johnson syndrome) <u>and acute generalised exanthematous pustulosis</u> may occur. Patients should be carefully monitored, and appropriate measures should be taken if symptoms such as pyrexia, erythema, <u>small pustules</u>, pruritus, ocular hyperaemia, or stomatitis are observed.</p>

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