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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 Ioversol

May 9, 2023

Therapeutic category

X-ray contrast agents

Non-proprietary name

Ioversol

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
<p>Adverse Reactions</p> <p>Clinically Significant Adverse Reactions</p> <p>Skin disorders:</p> <p>Oculomucocutaneous syndrome (Stevens-Johnson syndrome), <u>etc.</u> 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 disorders:</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 Electronic Package Inserts of Prescription Drugs, etc. PSEHB Notification No. 0611-1 by the Director-General of Pharmaceutical Safety and Environmental Health Bureau, MHLW, dated June 11, 2021 (New instructions):

Revised language is underlined.

Current	Revision
<p>11. ADVERSE REACTIONS</p> <p>11.1 Clinically Significant Adverse Reactions</p> <p>Skin disorders</p> <p>Oculomucocutaneous syndrome (Stevens-Johnson syndrome), <u>etc.</u> 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>Skin disorders</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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