

Published by
Ministry of Health, Labour and Welfare



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

Iohexol (preparations with indications of cerebral angiography, angiocardiology (including pulmonary artery angiography), aortography, and angiocardiology of pediatrics (including pulmonary artery angiography))

July 20, 2020

Therapeutic category

X-ray contrast media

Non-proprietary name

Iohexol

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 Clinically Significant Adverse Reactions (N/A)</p>	<p>Adverse Reactions Clinically Significant Adverse Reactions <u>Contrast-induced encephalopathy:</u> <u>Disturbed consciousness, paralysis, aphasia, cortical blindness, or other central nervous system symptoms may occur as a result of extracerebrovascular leakage of this drug in cerebral angiography, angiocardiology (including pulmonary artery angiography), aortography, and angiocardiology of pediatrics (including pulmonary artery angiography). Minimum effective dosages should be administered and appropriate measures should be taken if any abnormalities are observed.</u></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 11.1 Clinically Significant Adverse Reactions (N/A)</p>	<p>11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions <u>(Cerebral angiography, angiocardiology (including pulmonary artery angiography), aortography, and angiocardiology of pediatrics (including pulmonary artery angiography))</u> <u>Contrast-induced encephalopathy</u></p>

Pharmaceuticals and Medical Devices Agency

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

	<p><u>Disturbed consciousness, paralysis, aphasia, cortical blindness, or other central nervous system symptoms may occur as a result of extracerebrovascular leakage of this drug. Minimum effective dosages should be administered and appropriate measures should be taken if any abnormalities are observed.</u></p>
--	--

N/A: Not Applicable, because the section is not included in the current package insert.

Pharmaceuticals and Medical Devices Agency

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