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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**

lohexol (preparations with indications of cerebral angiography, angiocardiography (including pulmonary artery angiography), aortography, and angiocardiography 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** 

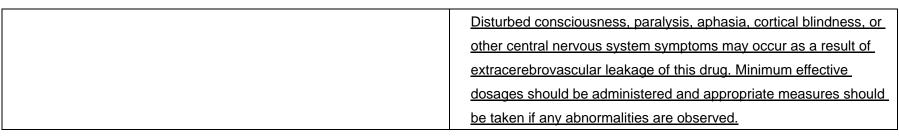
Revision in line with the Instructions for Package Inserts of Prescription Drugs, PAB Notification No. 606 by the Director General of Pharmaceutical Affairs Bureau, MHW, dated April 25, 1997 (Old instructions):

Revised language is underlined.

Current	Revision
Adverse Reactions	Adverse Reactions
Clinically Significant Adverse Reactions	Clinically Significant Adverse Reactions
(N/A)	Contrast-induced encephalopathy:
	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,
	angiocardiography (including pulmonary artery angiography),
	aortography, and angiocardiography of pediatrics (including
	pulmonary artery angiography). Minimum effective dosages should
	be administered and appropriate measures should be taken if any
	abnormalities are observed.

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
11. ADVERSE REACTIONS	11. ADVERSE REACTIONS
11.1 Clinically Significant Adverse Reactions	11.1 Clinically Significant Adverse Reactions
(N/A)	(Cerebral angiography, angiocardiography (including pulmonary
	artery angiography), aortography, and angiocardiography of
	pediatrics (including pulmonary artery angiography))
	Contrast-induced encephalopathy



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