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Revision of Precautions

Iopromide

July 20, 2020

Therapeutic category

X-ray contrast media

Non-proprietary name

Iopromide

Safety measure

Precautions should be revised in the package insert.

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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 Disturbed consciousness, paralysis, aphasia, cortical blindness, or other contrast-induced encephalopathy symptoms may occur as a result of extracerebrovascular leakage of this drug in cerebral angiography, thoracic aortography, and angiocardiography. 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 11.1 Clinically Significant Adverse Reactions (N/A)	11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions (Cerebral angiography, thoracic aortography, and angiocardiography) 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. Minimum effective

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	dosages should be administered and appropriate measures should be taken if any abnormalities are observed.

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