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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 Aminolevulinic acid hydrochloride

February 25, 2020

Therapeutic category

Intracorporeal diagnostic agents-miscellaneous

Non-proprietary name

Aminolevulinic acid hydrochloride

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)	<u>Hypotension</u>
	Hypotension may occur. Patients should be carefully monitored and
	appropriate measures should be taken if any abnormalities are
	observed. Cases of hypotension prolonged after surgery have been
	reported in which continuous administration of vasopressor was
	required.

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