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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

Aminolevulinic acid hydrochloride

January 6, 2022

Therapeutic category

Other diagnostic agents

Non-proprietary name

Aminolevulinic acid hydrochloride

Safety measure

Precautions should be revised in the package insert.

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>Contraindications</p> <p><u>Patients receiving drugs known to cause photosensitivity:</u></p> <p><u>Tetracyclines, sulfonamides, fluoroquinolones, hypericin (St. John's Wort extract), etc., or food containing St. John's Wort</u></p>			<p>Contraindications</p> <p>(deleted)</p>
<p>Drug Interactions</p> <p>Contraindications for Co-administration</p>			<p>Drug Interactions</p> <p>(deleted)</p>
Drugs	Signs, Symptoms, and Treatment	Mechanism and Risk Factors	
<p><u>Drugs known to cause photosensitivity:</u></p> <p><u>Tetracyclines,</u></p> <p><u>sulfonamides,</u></p> <p><u>fluoroquinolones,</u></p> <p><u>hypericin (St. John's Wort extract), etc.</u></p>	<p><u>Photosensitivity may occur.</u></p> <p><u>Administration of the drugs or ingestion of the food listed on the left-hand side should be avoided for 2 weeks after administration of this drug.</u></p>	<p><u>This drug is metabolized <i>in vivo</i> into a photo-sensitive substance. Co-administration of the drugs or ingestion of the food listed on the left-hand side may enhance photosensitivity.</u></p>	
<p><u>Food containing St. John's Wort</u></p>			

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<p>Precautions for Co-administration (N/A)</p>	<p>Precautions for Co-administration</p>		
	<p>Drugs</p>	<p>Signs, Symptoms, and Treatment</p>	<p>Mechanism and Risk Factors</p>
<p><u>Drugs known to cause photosensitivity: Tetracyclines, sulfonamides, or fluoroquinolones</u></p>	<p><u>Caution should be exercised for photosensitivity that may occur.</u> <u>For 48 hours after administration of this drug particularly,</u></p>	<p><u>This drug is metabolized <i>in vivo</i> into a photo-sensitive substance. Co-administration of the drugs or ingestion of the food listed on the left-hand side may</u></p>	
<p><u>Food containing St. John's Wort</u></p>	<p><u>administration of the drugs or ingestion of the food listed on the left-hand side should preferably be avoided as much as possible.</u></p>	<p><u>enhance photosensitivity.</u></p>	

N/A: Not Applicable. No corresponding language is included in the current package insert.

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