

This document is an English-translated version of an attachment of a notification for Revision of PRECAUTIONS issued by the Ministry of Health, Labour and Welfare.

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

Epoprostenol sodium

July 17, 2024

Therapeutic category

Other cardiovascular agents

Non-proprietary name

Epoprostenol sodium

Safety measure

PRECAUTIONS should be revised.

Pharmaceuticals and Medical Devices Agency

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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 <u>Ascites</u> <u>If ascites is observed, the possibility that it may be due to this drug</u> <u>or other causes (right heart failure, liver disorder, etc.) should be</u> <u>considered. If this drug is suspected to be the cause after</u> <u>evaluating possible causes for ascites, appropriate measures</u> <u>should be taken such as dose reduction or discontinuation of this</u> <u>drug.</u>

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

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