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

3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan
E-mail: safety.info@pmda.go.jp

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

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