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Revision of Precautions

Epoprostenol sodium

July 9, 2019

Therapeutic category

Circulatory organ agents-miscellaneous

Non-proprietary name

Epoprostenol sodium

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
Adverse Reactions Clinically Significant Adverse Reactions (N/A)	Adverse Reactions Clinically Significant Adverse Reactions <u>Thrombocytopenia may occur. Patients should be carefully monitored through methods such as periodic clinical laboratory tests. If any abnormalities are observed, dose reduction, discontinuation of administration, or other appropriate measures should be taken.</u>

Revision in line with the Instructions for Package Inserts of Prescription Drugs, etc. PSEHB Notification No. 0608-1 by the Director General of Pharmaceutical Safety and Environmental Health Bureau, MHLW, dated June 8, 2017 (New instructions): Revised language is underlined.

Current	Revision
8. IMPORTANT PRECAUTIONS (N/A)	8. IMPORTANT PRECAUTIONS <u>Thrombocytopenia may occur. Patients should be carefully monitored through methods such as periodic clinical laboratory tests.</u>
11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions (N/A)	11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions <u>Thrombocytopenia</u>

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

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