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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

Prednisolone sodium phosphate

January 10, 2024

Therapeutic category

Adrenal hormone preparations

Non-proprietary name

Prednisolone sodium phosphate

Safety measure

PRECAUTIONS should be revised.

Pharmaceuticals and Medical Devices Agency

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Revision in line with the Instructions for Electronic Package Inserts of Prescription Drugs, PSEHB Notification No. 0611-1 by the Director-General of Pharmaceutical Safety and Environmental Health Bureau, MHLW, dated June 11, 2021 (New instructions):

Revised language is underlined.

| Current | Revision |
|-----------------------------------|--|
| 8. IMPORTANT PRECAUTIONS (N/A) | 8. IMPORTANT PRECAUTIONS <u>It has been reported that tumour lysis syndrome occurred when prednisolone preparations (oral dosage form and injections) were administered to patients with lymphoid tumours. If rapid electrolyte abnormalities, acute kidney injury, etc. are observed after administration of this drug, appropriate measures should be taken with consideration given to the possibility of tumour lysis syndrome.</u> |

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

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