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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

Dexamethasone (oral dosage form) (preparations indicated for multiple myeloma)

January 10, 2024

Therapeutic category

Adrenal hormone preparations

Non-proprietary name

Dexamethasone (oral dosage form) (preparations indicated for multiple myeloma)

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
<p>8. IMPORTANT PRECAUTIONS (N/A)</p> <p>11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions (N/A)</p>	<p>8. IMPORTANT PRECAUTIONS <u>Tumour lysis syndrome may occur. Patients should be carefully monitored by checking serum electrolyte levels, renal function, etc.</u></p> <p>11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions <u>Tumour lysis syndrome</u> <u>If any abnormalities are observed, appropriate measures (e.g., administration of physiological saline solution and/or hyperuricaemia therapeutic agents, and dialysis) should be taken, and patients should be carefully monitored until recovery from such symptoms.</u></p>

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

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