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Pharmaceuticals and Medical Devices Agency

Revision of PRECAUTIONS

Dexamethasone (oral dosage form) (preparations indicated for lymphoid tumours), dexamethasone sodium phosphate (injections), hydrocortisone, hydrocortisone sodium succinate (preparations indicated for lymphoid tumours), prednisolone (oral dosage form), prednisolone sodium succinate, methylprednisolone, methylprednisolone sodium succinate, methylprednisolone acetate

January 10, 2024

Therapeutic category

Adrenal hormone preparations

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Non-proprietary name

Dexamethasone (oral dosage form) (preparations indicated for lymphoid tumours)

Dexamethasone sodium phosphate (injections)

Hydrocortisone

Hydrocortisone sodium succinate (preparations indicated for lymphoid tumours)

Prednisolone (oral dosage form)

Prednisolone sodium succinate

Methylprednisolone

Methylprednisolone sodium succinate

Methylprednisolone acetate

Safety measure

PRECAUTIONS should be revised.

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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
Important Precautions (N/A)	Important Precautions <u>Tumour lysis syndrome may occur when this drug is administered to patients with lymphoid tumours. Patients should be carefully monitored by checking serum electrolyte levels, renal function, etc.</u>
Adverse Reactions Clinically Significant Adverse Reactions (N/A)	Adverse Reactions Clinically Significant Adverse Reactions <u>Tumour lysis syndrome:</u> <u>Tumour lysis syndrome may occur when this drug is administered to patients with lymphoid tumours. 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>

Note: Dexamethasone sodium phosphate (injections), prednisolone sodium succinate, and methylprednisolone acetate are designated as drugs requiring preparation of a Drug Guide for Patients.

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

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.

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Current	Revision
8. IMPORTANT PRECAUTIONS <Common to all indications> (N/A) 11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions (N/A)	8. IMPORTANT PRECAUTIONS <Common to all indications> Tumour lysis syndrome may occur when this drug is administered to patients with lymphoid tumours. Patients should be carefully monitored by checking serum electrolyte levels, renal function, etc. 11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions Tumour lysis syndrome Tumour lysis syndrome may occur when this drug is administered to patients with lymphoid tumours. 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.

Dexamethasone sodium phosphate (injections), prednisolone sodium succinate, and methylprednisolone acetate are designated as drugs requiring preparation of a Drug Guide for Patients.

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