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Pharmaceuticals and Medical Devices Agency

Revision of Precautions

Dexamethasone (oral dosage form) (preparations not indicated for pituitary suppression tests), dexamethasone palmitate

May 13, 2022

Therapeutic category

Adrenal hormone preparations

Non-proprietary name

Dexamethasone, dexamethasone palmitate

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 Electronic Package Inserts of Prescription Drugs, etc. PSEHB Notification No. 0611-1 by the Director 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 Cases of phaeochromocytoma crisis have been reported after dexamethasone preparations (oral dosage form and injections) were administered without recognizing concurrent phaeochromocytoma. If a marked elevation in blood pressure, headache, palpitation, etc. are observed after administration of this drug, appropriate measures should be taken with consideration given to the possible occurrence of phaeochromocytoma crisis.
9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS 9.1 Patients with Complication or History of Diseases, etc. (N/A)	9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS 9.1 Patients with Complication or History of Diseases, etc. Patients with phaeochromocytoma or paraganglioma and those with suspected phaeochromocytoma or paraganglioma Phaeochromocytoma crisis may occur.

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

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