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Pharmaceuticals and Medical Devices Agency

Revision of Precautions

Dexamethasone (oral dosage form) (preparations indicated for pituitary suppression tests)

May 13, 2022

Therapeutic category

Adrenal hormone preparations

Non-proprietary name

Dexamethasone

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
(N/A)	Precautions concerning Indications Prior to conducting dexamethasone suppression tests, the presence or absence of concurrent phaeochromocytoma or paraganglioma should be confirmed. If such complications are present, treatment of phaeochromocytoma or paraganglioma should be prioritized.
Careful Administration (N/A)	Careful Administration Patients with phaeochromocytoma or paraganglioma and those with suspected phaeochromocytoma or paraganglioma [Phaeochromocytoma crisis may occur.]
Important Precautions (N/A)	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.

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

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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
(N/A)	5. PRECAUTIONS CONCERNING INDICATIONS <Pituitary suppression tests> Prior to conducting dexamethasone suppression tests, the presence or absence of concurrent phaeochromocytoma or paraganglioma should be confirmed. If such complications are present, treatment of phaeochromocytoma or paraganglioma should be prioritized.
8. IMPORTANT PRECAUTIONS <Common to all indications> (N/A)	8. IMPORTANT PRECAUTIONS <Common to all indications> 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. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS

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9.1 Patients with Complication or History of Diseases, etc. (N/A)	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.