

Published by
Ministry of Health, Labour and Welfare



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

Betamethasone (suppositories), betamethasone acetate/betamethasone sodium phosphate, betamethasone sodium phosphate (enemas)

May 13, 2022

Therapeutic category

Adrenal hormone preparations

Non-proprietary name

Betamethasone, betamethasone acetate/betamethasone sodium phosphate, betamethasone sodium phosphate

Pharmaceuticals and Medical Devices Agency

3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan
E-mail: safety.info@pmda.go.jp

Safety measure

Precautions should be revised in the package insert.

Pharmaceuticals and Medical Devices Agency

3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan
E-mail: safety.info@pmda.go.jp

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
<p>8. IMPORTANT PRECAUTIONS (N/A)</p> <p>9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS 9.1 Patients with Complication or History of Diseases, etc. (N/A)</p>	<p>8. IMPORTANT PRECAUTIONS <u>Cases of phaeochromocytoma crisis have been reported after betamethasone preparations (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.</u></p> <p>9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS 9.1 Patients with Complication or History of Diseases, etc. <u>Patients with phaeochromocytoma or paraganglioma and those with suspected phaeochromocytoma or paraganglioma</u> <u>Phaeochromocytoma crisis may occur.</u></p>

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

Pharmaceuticals and Medical Devices Agency

3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan
E-mail: safety.info@pmda.go.jp