

This document is an English-translated version of an attachment of a notification for Revision of PRECAUTIONS issued by the Ministry of Health, Labour and Welfare.

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

Desmopressin acetate hydrate (nasal preparations)

June 24, 2025

Therapeutic category

Pituitary hormone preparations

Non-proprietary name

Desmopressin acetate hydrate (nasal preparations)

Safety measure

PRECAUTIONS should be revised.

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Revised language is underlined.

| Current | Revision |
|---|--|
| 9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS 9.1 Patients with Complication or History of Diseases, etc. Patients with a history of hypersensitivity to any of the ingredients contained in this drug | 9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS 9.1 Patients with Complication or History of Diseases, etc. Patients with a history of hypersensitivity to any of the ingredients contained in this drug <u>This drug should not be administered except in cases where such use is considered absolutely necessary for the treatment.</u> <u>Anaphylaxis may occur.</u> |
| 11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions (N/A) | 11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions <u>Anaphylaxis</u> |

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