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Summary of Investigation Results

Desmopressin acetate hydrate (oral dosage form, nasal preparations)

June 24, 2025

Non-proprietary name

a., b., c. desmopressin acetate hydrate (oral dosage form)

d., e. desmopressin acetate hydrate (nasal preparations)

Brand name (marketing authorization holder)

See attachment.

Japanese market launch

See attachment.

Indications

See attachment.

Summary of revisions

a. to c.

“Anaphylaxis” should be added to the 11.1 Clinically Significant Adverse Reactions section in 11. ADVERSE REACTIONS.

d., e.

1. A precautionary statement that "this drug should not be administered except in cases where such use is considered absolutely necessary for the treatment" should be added to the Patients with a history of hypersensitivity to any of the ingredients contained in this drug sub-section in the 9.1 Patients with Complication or History of Diseases, etc. section of 9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS.
2. “Anaphylaxis” should be added to the 11.1 Clinically Significant Adverse Reactions

section in 11. ADVERSE REACTIONS.

Investigation results and background of the revision

Cases involving anaphylaxis were evaluated. As a result of consultation with expert advisors regarding the causality assessment of the cases and the necessity of revision of PRECAUTIONS, the MHLW/PMDA concluded that revision of PRECAUTIONS for oral dosage forms and nasal preparations of desmopressin acetate hydrate was necessary, since cases for which a causal relationship between desmopressin acetate hydrate (injections) and anaphylaxis was reasonably possible have been reported (revisions of PRECAUTIONS, dated April 8, 2005).

Of note, with consideration given to the opinions from the expert advisors, the MHLW/PMDA concluded that, for the nasal preparations, no description should be added to 2. CONTRAINDICATIONS. (This drug is contraindicated to the following patients.) Instead, a precautionary statement that "this drug should not be administered except in cases where such use is considered absolutely necessary for the treatment" should be added to the 9.1 Patients with Complication or History of Diseases, etc. section, for the following reasons: There are no alternative drugs for the nasal preparation indicated for central diabetes insipidus (d.), and therefore it is considered that specifying a contraindication could disadvantage patients in clinical settings.

Reference: Number of cases* and patient mortalities involving anaphylaxis reported in Japan and overseas

a., b., c.,

A total of 3 cases have been reported in Japan to date. (A causal relationship between the drug and the event could not be established for any of these cases.)

No patient mortalities have been reported in Japan to date.

A total of 3 cases have been reported overseas to date. (A causal relationship between the drug and the event could not be established for any of these cases.)

No patient mortalities have been reported overseas to date.

d., e.

One case has been reported in Japan to date. (A causal relationship between the drug and the event could not be established for this case.)

No patient mortalities have been reported in Japan to date.

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A total of 3 cases have been reported overseas to date. (A causal relationship between the drug and the event could not be established for any of these cases.)
No patient mortalities have been reported overseas to date.

* Cases collected in the PMDA's database for adverse drug reactions, etc. reports

The expert advisors present at the Expert Discussion regarding the current investigation were nominated based on their conflict of interest declarations concerning the relevant products, pursuant to the “Rules for Convening Expert Discussions, etc., by the Pharmaceuticals and Medical Devices Agency” (PMDA Administrative Rule No. 20-8, dated December 25, 2008).

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Attachment

No.	Non-proprietary Name	Brand name	Marketing authorization holder	Japanese market launch	Indications
a.	Desmopressin acetate hydrate	Minirinmelt OD Tablets 25 μg, 50 μg	Ferring Pharmaceuticals Co., Ltd.	September 2019	Treatment of nocturia due to nocturnal polyuria in males
b.	Desmopressin acetate hydrate	Minirinmelt OD Tablets 60 μg	Ferring Pharmaceuticals Co., Ltd.	March 2013	Central diabetes insipidus
c.	Desmopressin acetate hydrate	Minirinmelt OD Tablets 120 μg, 240 μg	Ferring Pharmaceuticals Co., Ltd.	May 2012	Central diabetes insipidus Nocturnal enuresis associated with decreased urine osmolarity or urinary specific gravity
d.	Desmopressin acetate hydrate	Desmopressin Nasal Spray 2.5 μg “Ferring”	Ferring Pharmaceuticals Co., Ltd.	October 1999	Central diabetes insipidus
e.	Desmopressin acetate hydrate	Desmopressin Spray 10 Kyowa and the others	Ferring Pharmaceuticals Co., Ltd. and the others	June 2003	The following disease associated with decreased urine osmolality or urinary specific gravity: Nocturnal enuresis