独立行政法人 医薬品医療機器総合機構
Pharmaceuticals and Medical Devices Agency

This English version is intended to be a reference material for the convenience of users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

Summary of Investigation Results

Desmopressin acetate hydrate (injections)

April 8, 2025

Non-proprietary name

Desmopressin acetate hydrate

Brand name (marketing authorization holder)

Desmopressin I.V. Injection 4 μg “Ferring” (Ferring Pharmaceuticals Co., Ltd.)

Japanese market launch

December 1988

Indications

Control of haemostasis for the following diseases associated with spontaneous haemorrhage, traumatic haemorrhage, and haemorrhage at the time of tooth extraction or during surgery

・Mild/moderate haemophilia A (patients whose factor VIII coagulation activity is 2% or higher)

・Type I/Type IIA von Willebrand's disease (VWD)

Summary of revisions

“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. Cases for which a causal relationship between desmopressin acetate hydrate (injections) and anaphylaxis was reasonably possible have been reported. 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 was necessary.

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

No cases have been reported in Japan to date.

A total of 13 cases have been reported overseas to date (including 5 cases for which a causal relationship between the drug and the event was reasonably possible).

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).