

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Desmotabs Melt 120 micrograms oral lyophilisate

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each unit contains 120 micrograms desmopressin (free base), present as desmopressin acetate.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral lyophilisate

Product imported from *France* and *Romania*:

White, round, oral lyophilisate marked with two drop shaped figures on one side.

4 CLINICAL PARTICULARS

As per PA1009/007/003

5 PHARMACOLOGICAL PROPERTIES

As per PA1009/007/003

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Gelatin
Mannitol
Citric Acid, anhydrous

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf-life expiry date of this product is the date shown on the container and outer carton of the product as marketed in the country of origin.

6.4 Special precautions for storage

Store below 25°C. Store in the original package in order to protect from moisture and light.

6.5 Nature and contents of container

Aluminium/aluminium blisters of 10 oral lyophilisates in pack sizes of 30 oral lyophilisates.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements

7 PARALLEL PRODUCT AUTHORISATION HOLDER

IMED Healthcare Ltd.
Unit 625 Kilshane Avenue
Northwest Business Park
Ballycoolin
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Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/174/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 2nd July 2021

10 DATE OF REVISION OF THE TEXT

April 2024