

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 Greece, Czech Republic 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 shall be the date shown on the container and outer package of the product on the market in the country of origin.

6.4 Special precautions for storage

Do not store above 25 °C.
Store in the original package in order to protect from moisture and light.

6.5 Nature and contents of container

Blisters of 30 oral lyophilisates.

6.6 Special precautions for disposal and other handling

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

PCO Manufacturing Ltd.
Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/260/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 8th July 2011

10 DATE OF REVISION OF THE TEXT

July 2023