Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

FROVEX 2.5 mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 2.5 mg of frovatriptan (as succinate monohydrate).

Excipient with known effect: lactose

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet.

Product imported from Greece:
Round biconvex white film-coated tablet, debossed with "m" on one side and "2.5" on the other.

4 CLINICAL PARTICULARS

As per PA1113/037/001

5 PHARMACOLOGICAL PROPERTIES

As per PA1113/037/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core
Lactose, anhydrous
Microcrystalline cellulose
Silica, colloidal anhydrous
Sodium starch glycollate *(*Type A)
Magnesium stearate

Tablet Coat
Opadry white:
Hypromellose (E 464)
Titanium dioxide (E 171)
Lactose, anhydrous
Macrogol 3000
Triacetin

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

Do not store above 30°C.
Store in the original package in order to protect from moisture.

6.5 Nature and contents of container

PVC/PE/PVDC//Aluminium blisterpacks with 6 tablets.

6.6 Special precautions for disposal

No special requirements. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

IMED Healthcare Ltd.,
Unit 625 Kilshane Avenue
Northwest Business Park
Ballycoolin
Dublin 15
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/262/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 6th July 2026

10 DATE OF REVISION OF THE TEXT

October 2026