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(s) with known effects: lactose
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet.

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

Product imported from Italy
Round, biconvex, white film-coated tablet, debossed with "m" on one side and "2,5" on the other.

4 CLINICAL PARTICULARS

As per PA 0865/009/001

5 PHARMACOLOGICAL PROPERTIES

As per PA 0865/009/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

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

Film 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 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 30 °C.
Store in the original package in order to protect from moisture.

6.5 Nature and contents of container

Blister packs with 6 tablets in a cardboard carton

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

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/321/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: July 2013
Last updated: January 2017

10 DATE OF REVISION OF THE TEXT

January 2022