

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Imigran Ftab 50 mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Tablets containing 50 mg of sumatriptan base as the succinate salt.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet.

Product imported from Spain and Italy:

Pink film-coated, triangular shaped, biconvex, tablet debossed "GS 1YM" on one face and "50" on the other.

4 CLINICAL PARTICULARS

As per PA1077/008/006

5 PHARMACOLOGICAL PROPERTIES

As per PA1077/008/006

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Calcium Hydrogen Phosphate Anhydrous
Microcrystalline cellulose
Sodium Hydrogen Carbonate
Croscarmellose sodium
Magnesium stearate
Hypromellose
Titanium dioxide (E171)
Triacetin
Red iron oxide (E172)

6.2 Incompatibilities

Not applicable

6.3 Shelf life

The shelf-life expiry date of this product is the date shown on the blister 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.

6.5 Nature and contents of container

Foil blister packs in a cardboard carton containing 4 or 6 tablets.

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 MARKETING AUTHORISATION HOLDER

Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath
Ireland

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 MARKETING AUTHORISATION NUMBER

PPA0465/070/003

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/070/003

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 17th April 2009

10 DATE OF REVISION OF THE TEXT

April 2021