

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Imigran Ftab 100mg Film-coated Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Tablets containing 100mg 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 Italy.

White film-coated, triangular shaped, biconvex tablet debossed "GS YE7" on one face and "100" on the other.

4 CLINICAL PARTICULARS

As per PA1077/008/007.

5 PHARMACOLOGICAL PROPERTIES

As per PA1077/008/007.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core

dibasic calcium phosphate, anhydrous
microcrystalline cellulose,
sodium bicarbonate,
croscarmellose sodium,
magnesium stearate,
hypromellose,
titanium dioxide (E171)
glycerol triacetate

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date for this product shall be 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

Blister packs, contained in a cardboard carton.
Pack sizes: 2, 4 or 6 film-coated 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 PARALLEL PRODUCT AUTHORISATION HOLDER

LTT Pharma Limited
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8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1562/188/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st March 2017

10 DATE OF REVISION OF THE TEXT