

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Imigran Ftab 100 mg Film-coated Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Tablets containing 100 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 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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Anhydrous dibasic calcium phosphate
Cellulose microcrystalline
Sodium bicarbonate
Croscarmellose sodium
Magnesium stearate
Hypromellose
Titanium oxide (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

Foil blister packs, contained in a cardboard carton.
Pack sizes 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 PARALLEL PRODUCT AUTHORISATION HOLDER

Lexon Pharmaceuticals (Ireland) Limited
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8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA23176/032/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 28th August 2020

10 DATE OF REVISION OF THE TEXT

October 2021