Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Imigran 20 mg Nasal Spray, Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each nasal applicator contains 20 mg of sumatriptan in 0.1 ml of solution.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Nasal spray, solution.

Product imported from France
A clear, pale to dark yellow, buffered solution.

4 CLINICAL PARTICULARS

As per PA1077/008/004

5 PHARMACOLOGICAL PROPERTIES

As per PA1077/008/004

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Potassium Dihydrogen Phosphate
Disodium Phosphate anhydrous
Sulphuric Acid
Sodium Hydroxide
Purified Water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date of 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.
Store in the original package in order to protect from light.
Do not freeze.

6.5 Nature and contents of container

Each unit dose spray device containing 0.1 ml solution is presented in an individually sealed blister.
Each carton contains 2 or 6 blisters.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/070/005

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 23rd February 2024

10 DATE OF REVISION OF THE TEXT