

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Zomig 2.5 mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 2.5 mg of zolmitriptan.

Excipient(s) with known effect:

Each tablet contains 100 mg lactose anhydrous.

For the full list of excipients, see Section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet.

Product imported from *France*.

Yellow in colour embossed with the letter 'Z' on one side.

4 CLINICAL PARTICULARS

As per PA2242/004/001

5 PHARMACOLOGICAL PROPERTIES

As per PA2242/004/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose anhydrous
Microcrystalline cellulose
Sodium carboxymethyl starch
Magnesium stearate
Macrogol 8000
OPARDY yellow OY-22906

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 25°C.

6.5 Nature and contents of container

Tablets in blister packs containing: 6 tablets. The blister strip is polyamide A1-PVC/A1

6.6 Special precautions for disposal and other handling

No special requirements.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

IMED Healthcare Ltd.
Unit 625 Kilshane Avenue
Northwest Business Park
Ballycoolin
Dublin 15
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/168/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 4th April 2021

10 DATE OF REVISION OF THE TEXT

March 2022