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: Contains lactose anhydrous.

For the full list of excipients, see Section 6.1

3 PHARMACEUTICAL FORM

Film-coated tablet

For tablets sourced in France, Italy, Portugal and Spain:
Round, biconvex, pale yellow, film-coated tablet, with 'Z' on one side and plain on the other.

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 starch glycolate
Magnesium stearate
Hypromellose
Macrogol
Iron Oxide yellow (E172)
Titanium dioxide (E171)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date for 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. Store in the original package.

6.5 Nature and contents of container

3, 6 or 12 tablets (with or without wallet)

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements. Any unused product or waste material should be disposed of in accordance with local requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/099/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 02 May 2003

Date of last renewal: 02 May 2008

10 DATE OF REVISION OF THE TEXT

April 2023