Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Zomig 2.5mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 2.5mg of zolmitriptan.

Excipient(s) with known effect: Also includes lactose anhydrous.

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Film-coated tablet

Product imported from France, the UK, Italy and Portugal:
Round, biconvex, pale yellow, film coated tablet with ‘Z’ on one side, plain on the other.

4 CLINICAL PARTICULARS

As per PA0970/026/001

5 PHARMACOLOGICAL PROPERTIES

As per PA0970/026/001

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 30°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 of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

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
Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath

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

May 2017