Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Zomig 2.5 mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 2.5mg zolmitriptan

Excipients: Lactose

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film coated tablet.

Product imported from France:
Round, biconvex, pale-yellow, film-coated tablet with ‘Z’ on one side and 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

Macrogol 8000
Opadry yellow OY-22906
Lactose anhydrous
Microcrystalline Cellulose
Sodium Starch Glycolate (Type A)
Magnesium Stearate

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 30°C.

6.5 Nature and contents of container

Tablets in blister packs containing: 6 tablets (with wallet)
The blister strip is polyamide AI-PVC/AI.

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

B&S Healthcare
Unit 4
Bradfield Road
Ruislip
Middlesex
HA4 0NU
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1328/005/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of First Authorisation: 18 August 2006

Date of Last Renewal: 18 August 2011

10 DATE OF REVISION OF THE TEXT

February 2015