

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Zomig Rapimelt 2.5 mg Orodispersible Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each orodispersible tablet contains 2.5 mg of zolmitriptan.

Excipients with known effect:

Each orodispersible tablet contains aspartame (E951).

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Orodispersible tablet

For tablets sourced in France, Portugal, The Netherlands and Spain:

Round, white uncoated orodispersible tablets impressed with 'Z' on one side with a bevelled edge.

4 CLINICAL PARTICULARS

As per PA2242/004/002

5 PHARMACOLOGICAL PROPERTIES

As per PA2242/004/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Mannitol (E421)

Microcrystalline cellulose

Aspartame (E951)

Sodium hydrogen carbonate

Anhydrous citric acid

Silica, Colloidal anhydrous

Orange Flavour – SN027512

Magnesium Stearate

Crospovidone

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf-life expiry date of this product is 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

Blister packs containing 2, 6 or 12 tablets.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements for disposal.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/099/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 23 November 2005

Date of last authorisation: 23 November 2010

10 DATE OF REVISION OF THE TEXT

September 2022