# 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

*Product imported from France, Portugal, The Netherlands and the UK:*
Round, white uncoated orodispersible tablets 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
Colloidal anhydrous silica
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 of a used medicinal product or waste materials derived from such medicinal product and other handling of the product**

The blister pack should be peeled open as shown on the foil (tablets should not be pushed through the foil).

**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**

April 2020