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.

Excipient with known effect: aspartame (E951).

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Orodispersible tablet.

Product imported from *France*.
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

Aspartame (E951)
Anhydrous Citric acid
Silica, Colloidal Anhydrous
Crospovidone
Magnesium stearate
Mannitol (E421)
Microcrystalline Cellulose
Orange Flavour - SN027512
Sodium hydrogen carbonate

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.

6.5 Nature and contents of container

Tablets in peelable aluminium laminate blister packs containing 6 tablets.

6.6 Special precautions for disposal and other handling

The blister pack should be peeled open as shown on the foil (tablets should not be pushed through the foil). No special requirements for disposal.
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

IMED Healthcare Ltd.
Unit 625 Kilshane Avenue
Northwest Business Park
Ballycoolin
Dublin 15
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/168/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 4th June 2021

10 DATE OF REVISION OF THE TEXT