

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

RELPAX 40 mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 40 mg eletriptan (as hydrobromide).

Excipients with known effect:

Each film-coated tablet contains lactose and Sunset yellow

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet.

Product imported from France:

Round, convex orange tablets debossed with 'REP 40' on one side and 'VLE' on the other.

4 CLINICAL PARTICULARS

As per PA23055/002/002

5 PHARMACOLOGICAL PROPERTIES

As per PA23055/002/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Core Tablet:

Microcrystalline cellulose

Lactose monohydrate

Croscarmellose sodium

Magnesium stearate.

Film Coating:

Titanium dioxide (E171)

Hypromellose

Lactose monohydrate

Glycerol triacetate

Sunset Yellow FCF Aluminium Lake (E110)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life of this product shall be the date shown on the blister and outer package of the product on the market in the country of origin.

6.4 Special precautions for storage

This product does not require any special storage conditions.

6.5 Nature and contents of container

Opaque PVC/Aclar/Aluminium blister packs containing 6 tablets.

6.6 Special precautions for disposal

Any unused 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
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Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/253/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 14th November 2025

10 DATE OF REVISION OF THE TEXT