

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 Italy

Round, convex orange tablets debossed with 'REP 40' on one side and 'Pfizer' 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

Microcrystalline cellulose

Lactose monohydrate

Croscarmellose sodium

Magnesium stearate

Titanium dioxide (E171)

Hypromellose,

Glycerol triacetate

Sunset yellow FCF

Aluminium lake (E110)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date for 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

Opaque PVC/Aclar/Aluminium blister: this medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

Opaque PVC/Aclar/Aluminium blister pack size 6 tablets.

6.6 Special precautions for disposal and other handling

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Lexon Pharmaceuticals (Ireland) Limited
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8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA23176/009/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 28th July 2017

10 DATE OF REVISION OF THE TEXT

November 2022