

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Sabril 500mg Film Coated Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 500mg vigabatrin

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film coated tablet

Product as imported from UK and the Czech Republic:

White, oval biconvex film-coated tablets with a breakline on one side and 'SABRIL' on the other.

The scoreline is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

4 CLINICAL PARTICULARS

As per PA0540/023/001

5 PHARMACOLOGICAL PROPERTIES

As per PA0540/023/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core

Povidone (E1201)

Microcrystalline cellulose (E460)

Sodium starch glycollate (type A)

Magnesium Stearate

Film coat

Hypromellose 15 mPa.s (E464)

Titanium dioxide (E171)

Macrogol 8000

6.2 Incompatibilities

Not applicable

6.3 Shelf life

The shelf-life expiry date of this product shall be 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 25°C.

6.5 Nature and contents of container

Container(s) : PVC /Aluminium foil blister packed in cardboard cartons.

Pack size : 100 tablets

6.6 Special precautions for disposal and other handling

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/203/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of First Authorisation: 1st February 2008
Last updated: August 2014.

10 DATE OF REVISION OF THE TEXT

August 2018.