

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Seroquel 100 mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Seroquel 100 mg contains 100 mg quetiapine (as quetiapine fumarate)

Excipients with known effect:

Seroquel 100 mg contains lactose (anhydrous)

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet.

Yellow coloured round biconvex film-coated tablets, engraved with SEROQUEL 100 on one side.

4 CLINICAL PARTICULARS

As per PA1019/019/002

5 PHARMACOLOGICAL PROPERTIES

As per PA1019/019/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core:

Povidone

Calcium hydrogen phosphate dihydrate

Microcrystalline cellulose

Sodium starch glycollate Type A

Lactose monohydrate

Magnesium stearate

Tablet coating:

Hypromellose

Macrogol

Titanium dioxide (E171)

Yellow iron oxide (E172)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date 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

Do not store above 30°C

6.5 Nature and contents of container

Seroquel film-coated tablets are packed in blisters in boxes 60 tablets.

6.6 Special precautions for disposal

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/438/006

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 4th December 2020