

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Seroquel 25 mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Seroquel 25 mg contains 25 mg quetiapine (as quetiapine fumarate)

Excipients: lactose monohydrate

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Film-coated tablet

Product imported from Italy and Austria

Peach coloured, round tablets engraved with 'SEROQUEL 25' on one side and plain on the other.

4 CLINICAL PARTICULARS

As per PA1019/019/001

5 PHARMACOLOGICAL PROPERTIES

As per PA1019/019/001

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

Film-Coating :

Hypromellose
Macrogol 400
Titanium Dioxide (E171)
Ferric Oxide Yellow (E172)
Ferric Oxide Red (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 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. Store in the original package.

6.5 Nature and contents of container

Cardboard outer containing blister strips. Pack size : 30 or 60 tablets.

6.6 Special precautions for disposal

No special requirements

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Imbat Limited
Unit L2
North Ring Business Park
Santry
Dublin 9
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1151/036/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st February 2008

10 DATE OF REVISION OF THE TEXT

November 2019