

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Seroquel 100mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Seroquel 100 mg contains 100 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: Spain
Seroquel 100mg tablets are yellow, round, biconvex tablets engraved with SEROQUEL 100 on one side and plain on the reverse.

4 CLINICAL PARTICULARS

As per PA0970/018/002

5 PHARMACOLOGICAL PROPERTIES

As per PA0970/018/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core:
Povidone
Calcium hydrogen phosphate dihydrate
Microcrystalline cellulose
Sodium starch glycolate 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 is the date shown on the blister and outer carton of the product as marketed in the country of origin.

6.4 Special precautions for storage

Do not store above 30°C.

6.5 Nature and contents of container

Blister packs of 60 tablets in an overlabeled outer carton.

6.6 Special precautions for disposal and other handling

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Imbat Ltd.
Unit L2
North Ring Business Park
Santry
Dublin 9

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1151/036/008

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 28th June 2012

10 DATE OF REVISION OF THE TEXT

May 2015