

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.

Product imported from *Greece*.

Seroquel 100 mg tablets are yellow, round biconvex and 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

Core:

Povidone

Calcium hydrogen phosphate dihydrate

Microcrystalline Cellulose

Sodium starch glycolate type A

Lactose Monohydrate

Magnesium Stearate

Coating:

Hypromellose

Macrogol 400

Titanium Dioxide (E171) Ferric Oxide, Yellow (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

PVC/aluminium blisters in a cardboard carton containing 60 tablets.

6.6 Special precautions for disposal

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

IMED Healthcare Ltd.
Unit 625 Kilshane Avenue
Northwest Business Park
Ballycoolin
Dublin 15
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/182/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 30th July 2021

10 DATE OF REVISION OF THE TEXT