

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)

Excipient : 20 mg lactose (anhydrous) per tablet

For a full list of excipients see section 6.1

3 PHARMACEUTICAL FORM

Film-coated tablet.

Product imported from Spain:

Seroquel 100 mg tablets are yellow, round biconvex and engraved with Seroquel 100 on one side.

4 CLINICAL PARTICULARS

As per PA0970/018/002.

5 PHARMACOLOGICAL PROPERTIES

As per PA0970/018/002.

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 on the product shall be the date shown on the container and outer packaging 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

Blisters in an overlabelled cardboard carton.

60 tablets (6 blisters of 10 tablets)

6.6 Special precautions for disposal

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Clear Pharmacy
157-173 Roden Street
Belfast BT12 5QA
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1596/010/005

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 3rd of December 2010

10 DATE OF REVISION OF THE TEXT

May 2015