

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Seroquel XR 400mg prolonged-release tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Seroquel XR 400mg contains 400mg quetiapine (as quetiapine fumarate)

Excipient: contains lactose monohydrate
For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Prolonged-Release Tablet

Product imported from Italy and the UK:
The tablets are white and engraved with “XR 400” on one side

4 CLINICAL PARTICULARS

As per PA0970/018/011

5 PHARMACOLOGICAL PROPERTIES

As per PA0970/018/011

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Core

Cellulose, microcrystalline
Sodium citrate
Lactose monohydrate
Magnesium stearate
Hypromellose

Coating

Hypromellose
Macrogol 400
Titanium dioxide (E171)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf-life expiry date of this product is 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. Keep in the original packaging.

6.5 Nature and contents of container

60 tablets in a carton, packaged as ten tablets per blister strip.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/153/007

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 20th May 2011

10 DATE OF REVISION OF THE TEXT

October 2014