

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Seroquel XR 50mg prolonged-release tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Seroquel XR 50 mg contains 50 mg quetiapine (as quetiapine fumarate)

Excipients with known effect:

Seroquel XR 50 mg contains lactose monohydrate

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Prolonged-release tablet

Product imported from Greece

Seroquel XR 50mg tablets are peach-coloured and engraved with "XR 50" on one side

4 CLINICAL PARTICULARS

As per PA1019/019/005

5 PHARMACOLOGICAL PROPERTIES

PA1019/019/005

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Core

Cellulose, microcrystalline

Sodium citrate

Lactose monohydrate

Magnesium stearate

Hypromellose

Coating

Hypromellose

Macrogol

Titanium dioxide (E171)

Iron oxide, yellow (E172)

Iron 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

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

Blisters in a cardboard carton containing 60 tablets.

6.6 Special precautions for disposal

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/438/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Last updated: October 2017

10 DATE OF REVISION OF THE TEXT

July 2019