Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Seroquel XR 150 mg prolonged-release tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Seroquel XR 150 mg contains 150 mg quetiapine (as quetiapine fumarate) Excipients with known effect: Seroquel XR 150 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 150mg tablets are white-coloured and engraved with "XR 150" on one side

4 CLINICAL PARTICULARS

As per PA2239/022/006

5 PHARMACOLOGICAL PROPERTIES

As per PA2239/022/006

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

<u>Core</u> Cellulose, microcrystalline Sodium citrate Lactose monohydrate Magnesium stearate Hypromellose

<u>Coating</u> Hypromellose Macrogol Titanium dioxide (E171)

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.

09 January 2024

Health Products Regulatory Authority

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

PPA0465/438/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Last updated: October 2017

10 DATE OF REVISION OF THE TEXT

January 2024