Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Seroquel XR 400 mg prolonged-release tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

Excipient(s) with known effect:

Seroquel XR 400 mg contains lactose monohydrate.
Seroquel XR 400 mg contains 27 mg sodium per tablet.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Prolonged-release tablet

Product imported from Greece:
Seroquel XR 400mg tablets are white and engraved with "XR 400" on one side.

4 CLINICAL PARTICULARS

As per PA2239/022/009

5 PHARMACOLOGICAL PROPERTIES

As per PA2239/022/009

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Core
Cellulose, microcrystalline
Sodium citrate
Lactose monohydrate
Magnesium stearate
Hypromellose

Coating
Hypromellose
Macrogol
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 blister 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

Blister pack containing 60 tablets - 6 blisters of 10 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

PPA0465/438/007

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 17th July 2026

10 DATE OF REVISION OF THE TEXT