

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Seroquel XR 200 mg prolonged-release tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Seroquel XR 200 mg contains 200 mg quetiapine (as quetiapine fumarate)

Excipient(s) with known effect:

Seroquel XR 200 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 200 mg tablets are yellow and engraved with "XR 200" on one side

## 4 CLINICAL PARTICULARS

As per PA2239/022/007

## 5 PHARMACOLOGICAL PROPERTIES

As per PA2239/022/007

## 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)

### 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**

PPA0465/438/003

### **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Last updated: October 2017

### **10 DATE OF REVISION OF THE TEXT**

March 2025