

## Summary of Product Characteristics

### 1 NAME OF THE MEDICINAL PRODUCT

Seroquel XR 50mg Prolonged-release Tablets

### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

Excipient: 119 mg lactose (anhydrous) per tablet

For a full list of excipients, see section 6.1.

### 3 PHARMACEUTICAL FORM

Prolonged-release Tablets

*Product imported from The Netherlands and the UK:*

Seroquel XR 50mg tablets are peach coloured and engraved with 'XR 50' on one side.

### 4 CLINICAL PARTICULARS

As per PA 0970/018/008

### 5 PHARMACOLOGICAL PROPERTIES

As per PA 0970/018/008

### 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**

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

#### **6.6 Special precautions for disposal**

No special requirements

### **7 PARALLEL PRODUCT AUTHORISATION HOLDER**

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

### **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA0465/153/008

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

Date of first authorisation: 5<sup>th</sup> August 2011

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

October 2014