

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Seroquel 100 mg film-coated tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Seroquel 100 mg contains 100 mg quetiapine (as quetiapine fumarate)

Excipients with known effect:

Seroquel 100 mg contains lactose (anhydrous)

For a full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Film-coated tablet.

*Product imported from Greece.*

Yellow coloured round biconvex film-coated tablets, engraved with SEROQUEL 100 on one side.

## 4 CLINICAL PARTICULARS

As per PA1019/019/002

## 5 PHARMACOLOGICAL PROPERTIES

As per PA1019/019/002

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Tablet core:

Povidone

Calcium hydrogen phosphate dihydrate

Microcrystalline cellulose

Sodium starch glycollate Type A

Lactose monohydrate

Magnesium stearate

Tablet coating:

Hypromellose

Macrogol

Titanium dioxide (E171)

Yellow iron oxide (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 blister and outer package of the product on the market in the country of origin.

### **6.4 Special precautions for storage**

Do not store above 30°C

### **6.5 Nature and contents of container**

Seroquel film-coated tablets are packed in blisters in boxes 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**

PPA0465/438/006

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

Date of first authorisation: 4<sup>th</sup> December 2020

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

November 2021