

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Seroquel 25 mg film-coated tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Seroquel 25 mg contains 25 mg quetiapine (as quetiapine fumarate)

Excipients with known effect:

Seroquel 25 mg contains lactose (anhydrous)

For a full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Film-coated tablet (tablet)

*Product imported from Greece:*

Peach coloured round bi convex film-coated tablets, engraved with SEROQUEL 25 logo on one side.

## 4 CLINICAL PARTICULARS

As per PA2239/022/001

## 5 PHARMACOLOGICAL PROPERTIES

As per PA2239/022/001

## 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)

Red 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**

PPA0465/438/005

### **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**

April 2025