

## 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)

Excipient: Also contains lactose

For a full list of excipients see section 6.1

### 3 PHARMACEUTICAL FORM

Film-coated tablet.

*Product imported from Italy:*

Seroquel 25 mg tablets are peach coloured, round biconvex and engraved with SEROQUEL 25 on one side.

### 4 CLINICAL PARTICULARS

As per PA0970/018/001

### 5 PHARMACOLOGICAL PROPERTIES

As per PA0970/018/001

### 6 PHARMACEUTICAL PARTICULARS

#### 6.1 List of excipients

##### Core

Povidone  
Calcium Hydrogen Phosphate Dihydrate  
Microcrystalline Cellulose  
Sodium Starch Glycolate Type A  
Lactose Monohydrate  
Magnesium Stearate

##### Coating

Hypromellose  
Macrogol  
Titanium Dioxide (E171)  
Ferric Oxide, Yellow (E172)  
Ferric Oxide, Red (E172)

#### 6.2 Incompatibilities

Not applicable.

### **6.3 Shelf life**

The shelf-life expiry date of this product is the date shown on the blister strips and outer carton 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**

Blisters in an overlabelled carton containing 60 tablets. (6 blisters of 10 tablets)

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

No special requirements.

## **7 PARALLEL PRODUCT AUTHORISATION HOLDER**

IMED Healthcare Ltd.  
Unit 625 Kilshane Avenue  
Northwest Business Park  
Ballycoolin  
Dublin 15  
Ireland

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA1463/048/002

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

Date of first authorisation: 24<sup>th</sup> August 2012

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

January 2016