

## Summary of Product Characteristics

### 1 NAME OF THE MEDICINAL PRODUCT

Quetiapine 25 mg film-coated tablets

### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 25 mg of quetiapine (as quetiapine hemifumarate).  
Excipient(s) with known effect: Each 25 mg film-coated tablet contains lactose monohydrate.

For the full list of excipients, see section 6.1.

### 3 PHARMACEUTICAL FORM

Film-coated tablet

*Product imported from The United Kingdom*

25mg tablets are pink coloured, round, biconvex, film-coated tablet, plain on both sides.

### 4 CLINICAL PARTICULARS

As per PA1390/027/001

### 5 PHARMACOLOGICAL PROPERTIES

As per PA1390/027/001

### 6 PHARMACEUTICAL PARTICULARS

#### 6.1 List of excipients

Lactose monohydrate  
Sodium starch glycolate (Type-A)  
Di basic calcium phosphate dihydrate  
Povidone K 30  
Cellulose microcrystalline  
Magnesium stearate

Film-coating:  
Opadry pink (03B84929)  
Hypromellose 6cP  
Titanium dioxide  
Macrogol 400  
Iron oxide yellow  
Iron oxide red

#### 6.2 Incompatibilities

Not applicable.

### **6.3 Shelf life**

The shelf life expiry date for 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**

This medicinal product does not require any special storage conditions.

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

PVC/Aluminium foil blisters in pack sizes of 60 tablets per carton.

### **6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product**

No special requirements.

## **7 PARALLEL PRODUCT AUTHORISATION HOLDER**

LTT Pharma Limited  
Unit 18  
Oxleasow Road  
East Moons Moat  
Redditch  
Worcestershire B98 0RE  
United Kingdom

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA1562/186/001

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

Date of first authorisation: 14<sup>th</sup> October 2016

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