

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Quetiapine 300 mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 300 mg of quetiapine (as quetiapine hemifumarate).
Excipient(s) with known effect: Each 300 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

300 mg tablets are white to off white, capsule shaped, biconvex, film-coated tablet, with ‘300’ debossed on one side and plain on other side.

4 CLINICAL PARTICULARS

As per PA1390/027/005

5 PHARMACOLOGICAL PROPERTIES

As per PA1390/027/005

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate,
Sodium starch glycolate (Type-A),
Di basic calcium phosphate dehydrate,
Povidone K 30,
Cellulose microcrystalline
Magnesium stearate (E470b).

Film-coating:
Hypromellose E-5
Macrogol 400
Titanium Dioxide

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
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United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1562/186/003

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 14th October 2016

10 DATE OF REVISION OF THE TEXT