

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Seroquel XR 400 mg prolonged-release tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Seroquel XR 400 mg contains 400 mg quetiapine (as quetiapine fumarate)

Excipient with known effect

Lactose

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Prolonged-release tablet

Product imported from Austria

Seroquel XR 400 mg tablets are white, capsule shaped and engraved with 'XR 400' on one side

4 CLINICAL PARTICULARS

As per PA1019/019/009

5 PHARMACOLOGICAL PROPERTIES

As per PA1019/019/009

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Core:

Microcrystalline cellulose

Sodium citrate

Lactose monohydrate

Magnesium stearate

Hypromellose

Coating:

Hypromellose

Macrogol 400

Titanium dioxide (E171)

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

Blisters of 60 tablets.

6.6 Special precautions for disposal

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Originalis B.V.
Joop Geesinkenweg 901
1114 AB Amsterdam-Duivendrecht
Netherlands

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA2306/011/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 15th February 2019

10 DATE OF REVISION OF THE TEXT