

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Seroquel XR 50 mg prolonged-release tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Seroquel XR 50 mg contains 50 mg quetiapine (as quetiapine fumarate)

Excipients with known effect:

Seroquel XR 50 mg contains lactose monohydrate.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Prolonged-release tablet

Product imported from Greece:

Seroquel XR 50 mg tablets are peach-coloured and engraved with "XR 50" on one side

4 CLINICAL PARTICULARS

As per PA2239/022/005

5 PHARMACOLOGICAL PROPERTIES

As per PA2239/022/005

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core:

microcrystalline cellulose

sodium citrate

lactose monohydrate

magnesium stearate

hypromellose

Tablet coating:

hypromellose

polyethylene glycol

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 container 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 in a cardboard carton containing 60 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

PPA1463/182/003

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 24th May 2024

10 DATE OF REVISION OF THE TEXT