

Summary Public Assessment Report

Quetiapin Orion (quetiapine fumarate)

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(quetiapine fumarate)

Film-coated tablet 25 mg, 100 mg, 200 mg and 300 mg

This is a summary of the public assessment report (PAR) for Quetiapin Orion. It explains how Quetiapin Orion was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Quetiapin Orion.

For practical information about using Quetiapin Orion, patients should read the package leaflet or contact their doctor or pharmacist.

What is Quetiapin Orion and what is it used for?

Quetiapin Orion is a 'generic medicine'. This means that Quetiapin Orion is similar to a 'reference medicine' already authorised in the European Union (EU) called Seroquel.

Quetiapin Orion can be used to treat several illnesses, such as:

- Bipolar depression: where you feel sad. You may find that you feel depressed, feel guilty, lack energy, lose your appetite or can't sleep.
- Mania: where you may feel very excited, elated, agitated, enthusiastic or hyperactive or have poor judgment including being aggressive or disruptive.
- Schizophrenia: where you may hear or feel things that are not there, believe things that are not true or feel unusually suspicious, anxious, confused, guilty, tense or depressed.

How does Quetiapin Orion work?

Quetiapin Orion contains a substance called quetiapine. This belongs to a group of medicines called antipsychotics.

How is Quetiapin Orion used?

The pharmaceutical form of Quetiapin Orion is film-coated tablet for oral use.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription.

What benefits of Quetiapin Orion have been shown in studies?

Because Quetiapin Orion is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Seroquel. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects of Quetiapin Orion?

Because Quetiapin Orion is a generic medicine and is bioequivalent to the reference medicine, its benefits and possible side effects are taken as being the same as the reference medicine. For the full list of restrictions, see the package leaflet.

Why is Quetiapin Orion approved?

It was concluded that, in accordance with EU requirements, Quetiapin Orion has been shown to have comparable quality and to be bioequivalent to the reference medicine Seroquel. Therefore, the Medical Products Agency in Sweden decided that, as for Seroquel, the benefits are greater than its risks and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of Quetiapin Orion?

A risk management plan has been developed to ensure that Quetiapin Orion is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Quetiapin Orion, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

Other information about Quetiapin Orion

The marketing authorisation for Quetiapin Orion was granted on 2019-01-28 in Sweden.

The full PAR for Quetiapin Orion can be found on the following website: <http://mri.medagencies.org/Human/>. For more information about treatment with Quetiapin Orion, please read the package leaflet for [25 mg](#), [100 mg](#), [200 mg](#), [300 mg](#) or contact your doctor or pharmacist.

This summary was last updated in 2019-03.