# Summary Public Assessment Report

# Generics

# Quetiapin KRKA
# Quetiapine (as quetiapine fumarate)

# DK/H/1059/009/DC

# Date: 07-12-2015

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# Quetiapin KRKA

## Quetiapin prolonged-release tablets 50 mg

This is a summary of the public assessment report (PAR) for Quetiapin KRKA. It explains how Quetiapin KRKA 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 KRKA.

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

**What is Quetiapin KRKA and what is it used for?**
Quetiapin KRKA is a 'generic medicine'. This means that Quetiapin KRKA is similar to a 'reference medicine' already authorised in the European Union (EU) called Seroquel Prolong.
Quetiapin KRKA is used in the treatment of:

- Bipolar depression and major depressive episodes in major depressive disorder: 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 judgement 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.

When Quetiapin KRKA is being taken to treat major depressive episodes in major depressive disorder, it will be taken in addition to another drug being used to treat this illness.

**How does Quetiapin KRKA work?**
Quetiapin KRKA belongs to a group of medicines called anti-psychotics and interferes with a number of the brain's transmitter substances.

**How is Quetiapin KRKA used?**
Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

**The usual dose is:**
The doctor will decide the starting dose. The maintenance dose will depend on the illness and needs but will usually be between 150 mg and 800 mg.
- The tablets must be taken once a day.
- The tablet must not be split, chewed or crushed.
- The tablets must be swallowed whole with a drink of water.
- The tablets must be taken without food (at least one hour before a meal or at bedtime)
- The tablets must not be taken with grapefruit juice. It can affect the way the medicine works.
- The tablets should be taken until the doctor stops the treatment.

**Liver problems**
The doctor may change the dose for patients with liver problems.

**Elderly people**
The doctor may change the dose for elderly patients.

**Use in children and adolescents**
Quetiapin KRKA should not be used by children and adolescents aged under 18 years.

The medicine can only be obtained with a prescription.

**What benefits of Quetiapin KRKA have been shown in studies?**
Because Quetiapin KRKA is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Seroquel Prolong. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.
The company provided data from the published literature on quetiapine.

**What are the possible side effects of Quetiapin KRKA?**
Because Quetiapin KRKA 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 KRKA approved?**
It was concluded that, in accordance with EU requirements, Quetiapin KRKA has been shown to have comparable quality and to be bioequivalent to Seroquel Prolong. Therefore, the member states involved in the procedure concluded that, as for Seroquel Prolong, the benefits are greater than its risk and recommended that it can be approved for use.

**What measures are being taken to ensure the safe and effective use of Quetiapin KRKA?**
A risk management plan has been developed to ensure that Quetiapin KRKA 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 KRKA, 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.

Additional measures in the form of health care professional educational materials are agreed for the following risks of Quetiapin KRKA:

- Extrapyramidal symptoms
- Somnolence
- Weight gain
- Lipid changes (increased cholesterol, increased triglycerides, or decreased HDLs)
- Hyperglycemia and diabetes mellitus
- Metabolic risk factors, metabolic syndrome

**Other information about Quetiapin KRKA**
The marketing authorisation for Quetiapin KRKA was granted on 26-11-2015.

The full PAR and the package leaflet for Quetiapin KRKA can be found on the website http://mri.medagencies.org/Human/. For more information about treatment with Quetiapin KRKA, read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 12-2015.