

# **Summary Public Assessment Report**

## **Generics**

### **Quetiapin "Hexal" (Quetiapine (as quetiapine fumarate))**

**DK/H/2334/001-005/DC**

**26 January 2016**

# Summary Public Assessment Report

## Quetiapin "Hexal"

### **Quetiapine, prolonged-release tablets, 50 mg, 150 mg, 200 mg, 300 mg, 400 mg**

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

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

#### **What is Quetiapin "Hexal" and what is it used for?**

Quetiapin "Hexal" is a 'generic medicine'. This means that Quetiapin "Hexal" is similar to a 'reference medicine' already authorised in the European Union (EU) called Seroquel Prolong. Quetiapin "Hexal" is used in the treatment of:

- Bipolar depression and major depressive episodes in major depressive disorder: where the patient feels sad. The patient may find that he/she feels depressed, feels guilty, lacks energy, loses appetite or cannot sleep.
- Mania: where the patient may feel very excited, elated, agitated, enthusiastic or hyperactive or have poor judgment including being aggressive or disruptive.
- Schizophrenia: where the patient may hear or feel things that are not there, believes things that are not true or feels unusually suspicious, anxious, confused, guilty, tense or depressed.

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

#### **How does Quetiapin "Hexal" work?**

Quetiapin "Hexal" belongs to a group of medicines called anti-psychotics and interferes with a number of the brain's transmitter substances.

#### **How is Quetiapin "Hexal" used?**

The pharmaceutical form of Quetiapin "Hexal" is prolonged-release tablets and the route of administration is oral.

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 "Hexal" 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 "Hexal" have been shown in studies?**

Because Quetiapin "Hexal" 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 "Hexal"?**

Because Quetiapin "Hexal" 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 "Hexal" approved?**

It was concluded that, in accordance with EU requirements, Quetiapin "Hexal" 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 "Hexal"?**

A risk management plan has been developed to ensure that Quetiapin "Hexal" 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 "Hexal", 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.

The marketing authorisation holder is obliged to provide educational materials to the health care professionals regarding the following risks of Quetiapin "Hexal":

- Extrapiramidal symptoms
- Somnolence
- Weight gain
- Lipid changes /increased cholesterol, increased triglycerides or decreased HDLs
- Hyperglycemia and diabetes mellitus
- Metabolic risk factors
- Potential for off-label use and misdosing

**Other information about Quetiapin "Hexal"**

The marketing authorisation for Quetiapin "Hexal" was granted on 10 March 2015.

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

This summary was last updated in 01-2016.