Package leaflet: Information for the patient

Quetiapine Krka 25 mg film-coated tablets
Quetiapine Krka 100 mg film-coated tablets
Quetiapine Krka 200 mg film-coated tablets
Quetiapine Krka 300 mg film-coated tablets
quetiapine

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Quetiapine Krka is and what it is used for

Quetiapine Krka contains a substance called quetiapine. This belongs to a group of medicines called antipsychotics. Quetiapine Krka 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.

Your doctor may continue to prescribe Quetiapine Krka even when you are feeling better.

2. What you need to know before you take Quetiapine Krka

DO NOT TAKE Quetiapine Krka
- if you are allergic to quetiapine or any of the other ingredients of this medicine (listed in section 6).
- if you are taking any of the following medicines:
    - some medicines for HIV
    - azole medicines (for fungal infections)
    - erythromycin or clarithromycin (for infections)
    - nefazodone (for depression).

If you are not sure, talk to your doctor or pharmacist before taking Quetiapine Krka.

Warnings and precautions
Talk to your doctor or pharmacist before taking Quetiapine Krka if:

- You or someone in your family, have or have had any heart problems, for example heart rhythm problems, weakening of the heart muscle or inflammation of the heart or if you are taking any medicines that may have an impact on the way your heart beats.
- You have low blood pressure.
- You have had a stroke, especially if you are elderly.
- You have problems with your liver.
- You have ever had a fit (seizure).
- You have diabetes or have a risk of getting diabetes. If you do, your doctor may check your blood sugar levels while you are taking Quetiapine Krka.
- You know that you have had low levels of white blood cells in the past (which may or may not have been caused by other medicines).
- You are an elderly person with dementia (loss of brain function). If you are, Quetiapine Krka should not be taken because the group of medicines that Quetiapine Krka belongs to may increase the risk of stroke or in some cases the risk of death in elderly people with dementia.
- You are an elderly person with Parkinson's disease/parkinsonism.
- You or someone else in your family has a history of blood clots, as medicines like these have been associated with formation of blood clots.
- You have or have had a condition where you stop breathing for short periods during your normal nightly sleep (called "sleep apnoea") and are taking medicines that slow down the normal activity of the brain ("depressants").
- You have or have had a condition where you can't completely empty your bladder (urinary retention), have an enlarged prostate, a blockage in your intestines, or increased pressure inside your eye. These conditions are sometimes caused by medicines (called "anti-cholinergics") that affect the way nerve cells function in order to treat certain medical conditions.
- You have a history of alcohol or drug abuse.
- You have depression or other conditions that are treated with antidepressants. The use of these medicines together with Quetiapine Krka can lead to serotonin syndrome, a potentially life-threatening condition (see "Other medicines and Quetiapine Krka").

Tell your doctor immediately if you experience any of the following after taking Quetiapine Krka:
- A combination of fever, severe muscle stiffness, sweating or a lowered level of consciousness (a disorder called "neuroleptic malignant syndrome"). Immediate medical treatment may be needed.
- Uncontrollable movements, mainly of your face or tongue.
- Dizziness or a severe sense of feeling sleepy. This could increase the risk of accidental injury (fall) in elderly patients.
- Fits (seizures).
- A long-lasting and painful erection (Priapism).
- Have a fast and irregular heartbeat, even when you are at rest, palpitations, breathing problems, chest pain or unexplained tiredness. Your doctor will need to check your heart and if necessary, refer you to a cardiologist immediately.

These conditions can be caused by this type of medicine.

Tell your doctor as soon as possible if you have:
- A fever, flu-like symptoms, sore throat or any other infection, as this could be a result of a very low white blood cell count, which may require Quetiapine Krka to be stopped and/or treatment to be given.
- Constipation along with persistent abdominal pain or constipation which has not responded to treatment, as this may lead to a more serious blockage of the bowel.

Thoughts of suicide and worsening of your depression
If you are depressed you may sometimes have thoughts of harming or killing yourself. These may be increased when first starting treatment, since these medicines all take time to work, usually about two

weeks but sometimes longer. These thoughts may also be increased if you suddenly stop taking your medication. You may be more likely to think like this if you are a young adult. Information from clinical trials has shown an increased risk of suicidal thoughts and/or suicidal behaviour in young adults aged less than 25 years with depression.

If you have thoughts of harming or killing yourself at any time, contact your doctor or go to a hospital straight away. You may find it helpful to tell a relative or close friend that you are depressed and ask them to read this leaflet. You might ask them to tell you if they think your depression is getting worse or if they are worried about changes in your behaviour.

Severe cutaneous adverse reactions (SCARs)
Severe cutaneous adverse reactions (SCARs) which can be life-threatening or fatal have been reported very rarely with treatment of this medicine. These are commonly manifested by:
- Stevens-Johnson syndrome (SJS), a widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals
- Toxic Epidermal Necrolysis (TEN), a more severe form causing extensive peeling of the skin
- Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) consists of flu-like symptoms with a rash, fever, swollen glands, and abnormal blood test results (including increased white blood cells (eosinophilia) and liver enzymes)
- Acute Generalized Exanthematous Pustulosis (AGEP), small blisters filled with pus
- Erythema Multiforme (EM), skin rash with itchy-red irregular spots

Stop using Quetiapine Krka if you develop these symptoms and contact your doctor or seek medical attention immediately.

Weight gain
Weight gain has been seen in patients taking Quetiapine Krka. You and your doctor should check your weight regularly.

Children and Adolescents
Quetiapine Krka is not for use in children and adolescents below 18 years of age.

Other medicines and Quetiapine Krka
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Do not take Quetiapine Krka if you are taking any of the following medicines:
- Some medicines for HIV.
- Azole medicines (for fungal infections).
- Erythromycin or clarithromycin (for infections).
- Nefazodone (for depression).

Tell your doctor if you are taking any of the following medicines:
- Epilepsy medicines (like phenytoin or carbamazepine).
- High blood pressure medicines.
- Barbiturates (for difficulty sleeping).
- Thioridazine or Lithium (other anti-psychotic medicines).
- Medicines that have an impact on the way your heart beats, for example, drugs that can cause an imbalance in electrolytes (low levels of potassium or magnesium) such as diuretics (water pills) or certain antibiotics (drugs to treat infections).
- Medicines that can cause constipation.
- Medicines (called “anti-cholinergics”) that affect the way nerve cells function in order to treat certain medical conditions.
- Anti-depressants. These medicines may interact with Quetiapine Krka and you may experience symptoms such as involuntary, rhythmic contractions of muscles, including the muscles that control movement of the eye, agitation, hallucinations, coma, excessive sweating, tremor,

exaggeration of reflexes, increased muscle tension, body temperature above 38°C (serotonin syndrome). Contact your doctor when experiencing such symptoms.

Before you stop taking any of your medicines, please talk to your doctor first.

Quetiapine Krka with food, drink and alcohol
- Quetiapine Krka can be taken with or without food.
- Be careful how much alcohol you drink. This is because the combined effect of Quetiapine Krka and alcohol can make you sleepy.
- Do not drink grapefruit juice while you are taking Quetiapine Krka. It can affect the way the medicine works.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. You should not take Quetiapine Krka during pregnancy unless this has been discussed with your doctor. Quetiapine Krka should not be taken if you are breast-feeding.

The following symptoms which can represent withdrawal may occur in newborn babies of mothers that have used Quetiapine Krka in the last trimester (last three months of their pregnancy): shaking, muscle stiffness and/or weakness, sleepiness, agitation, breathing problems, and difficulty in feeding. If your baby develops any of these symptoms you may need to contact your doctor.

Driving and using machines
Your tablets may make you feel sleepy. Do not drive or use any tools or machines until you know how the tablets affect you.

Quetiapine Krka contains lactose and sodium
Quetiapine Krka contains lactose which is a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially "sodium-free".

Effect on Urine Drug Screens
If you are having a urine drug screen, taking Quetiapine Krka may cause positive results for methadone or certain drugs for depression called tricyclic antidepressants (TCAs) when some test methods are used, even though you may not be taking methadone or TCAs. If this happens, a more specific test can be performed.

3. How to take Quetiapine Krka

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Your doctor will decide on your starting dose. The maintenance dose (daily dose) will depend on your illness and needs but will usually be between 150 mg and 800 mg.

- You will take your tablets once a day, at bedtime or twice a day, depending on your illness
- Swallow your tablets whole with a drink of water.
- You can take your tablets with or without food.
- Do not drink grapefruit juice while you are taking Quetiapine Krka. It can affect the way the medicine works.
- Do not stop taking your tablets even if you feel better, unless your doctor tells you.

Liver problems
If you have liver problems your doctor may change your dose.

Elderly
If you are elderly your doctor may change your dose.

Use in children and adolescents
Quetiapine Krka should not be used by children and adolescents aged under 18 years.

If you take more Quetiapine Krka than you should
If you take more Quetiapine Krka than prescribed by your doctor, you may feel sleepy, feel dizzy and experience abnormal heart beats. Contact your doctor or nearest hospital straight away. Keep the Quetiapine Krka tablets with you.

If you forget to take Quetiapine Krka
If you forget to take a dose, take it as soon as you remember. If it is almost time to take the next dose, wait until then. Do not take a double dose to make up for a forgotten tablet.

If you stop taking Quetiapine Krka
If you suddenly stop taking Quetiapine Krka, you may be unable to sleep (insomnia), or you may feel sick (nausea), or you may experience headache, diarrhoea, being sick (vomiting), dizziness or irritability. Your doctor may suggest you reduce the dose gradually before stopping treatment.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Very common: may affect more than 1 in 10 people
- Dizziness (may lead to falls), headache, dry mouth.
- Feeling sleepy (this may go away with time, as you keep taking Quetiapine Krka) (may lead to falls).
- Discontinuation symptoms (symptoms which occur when you stop taking Quetiapine Krka) include not being able to sleep (insomnia), feeling sick (nausea), headache, diarrhoea, being sick (vomiting), dizziness and irritability. Gradual withdrawal over a period of at least 1 to 2 weeks is advisable.
- Putting on weight.
- Abnormal muscle movements. These include difficulty starting muscle movements, shaking, feeling restless or muscle stiffness without pain.
- Changes in the amount of certain fats (triglycerides and total cholesterol).

Common: **may affect up to 1 in 10 people**
- Rapid heartbeat.
- Feeling like your heart is pounding, racing or has skipped beats.
- Constipation, upset stomach (indigestion).
- Feeling weak.
- Swelling of arms or legs.
- Low blood pressure when standing up. This may make you feel dizzy or faint (may lead to falls).
- Increased levels of sugar in the blood.
- Blurred vision.
- Abnormal dreams and nightmares.
- Feeling more hungry.
- Feeling irritated.
- Disturbance in speech and language.
- Thoughts of suicide and worsening of your depression.

- Shortness of breath.
- Vomiting (mainly in the elderly).
- Fever.
- Changes in the amount of thyroid hormones in your blood.
- Decreases in the number of certain types of blood cells.
- Increases in the amount of liver enzymes measured in the blood.
- Increases in the amount of the hormone prolactin in the blood. Increases in the hormone prolactin could in rare cases lead to the following:
    - Men and women to have swelling of breasts and unexpectedly produce breast milk.
    - Women to have no monthly period or irregular periods.

Uncommon: may affect up to 1 in 100 people
- Fits or seizures.
- Allergic reactions that may include raised lumps (weals), swelling of the skin and swelling around the mouth.
- Unpleasant sensations in the legs (also called restless legs syndrome).
- Difficulty swallowing.
- Uncontrollable movements, mainly of your face or tongue.
- Sexual dysfunction.
- Diabetes.
- Change in electrical activity of the heart seen on ECG (QT prolongation).
- A slower than normal heart rate which may occur when starting treatment and which may be associated with low blood pressure and fainting.
- Difficulty in passing urine.
- Fainting (may lead to falls).
- Stuffy nose.
- Decrease in the amount of red blood cells.
- Decrease in the amount of sodium in the blood.
- Worsening of pre-existing diabetes.
- Confusion.

Rare: may affect up to 1 in 1,000 people
- A combination of high temperature (fever), sweating, stiff muscles, feeling very drowsy or faint (a disorder called “neuroleptic malignant syndrome”).
- Yellowing of the skin and eyes (jaundice).
- Inflammation of the liver (hepatitis).
- A long-lasting and painful erection (priapism).
- Swelling of breasts and unexpected production of breast milk (galactorrhoea).
- Menstrual disorder.
- Blood clots in the veins especially in the legs (symptoms include swelling, pain and redness in the leg), which may travel through blood vessels to the lungs causing chest pain and difficulty in breathing. If you notice any of these symptoms seek medical advice immediately.
- Walking, talking, eating or other activities while you are asleep.
- Body temperature decreased (hypothermia).
- Inflammation of the pancreas.
- A condition (called “metabolic syndrome”) where you may have a combination of 3 or more of the following: an increase in fat around your abdomen, a decrease in “good cholesterol” (HDL-C), an increase in a type of fat in your blood called triglycerides, high blood pressure and an increase in your blood sugar.
- Combination of fever, flu-like symptoms, sore throat, or any other infection with very low white blood cell count, a condition called agranulocytosis.
- Bowel obstruction.
- Increased blood creatine phosphokinase (a substance from the muscles).

Very rare: may affect up to 1 in 10,000 people
- Severe rash, blisters or red patches on the skin.
- A severe allergic reaction (called anaphylaxis) which may cause difficulty in breathing or shock.
- Rapid swelling of the skin, usually around the eyes, lips and throat (angioedema).
- A serious blistering condition of the skin, mouth, eyes and genitals (Stevens-Johnson syndrome). See section 2.
- Inappropriate secretion of a hormone that controls urine volume.
- Breakdown of muscle fibers and pain in muscles (rhabdomyolysis).

Not known: frequency cannot be estimated from the available data
- Skin rash with irregular red spots (erythema multiforme). See section 2.
- Rapid appearance of areas of red skin studded with small pustules (small blisters filled with white/yellow fluid called as Acute generalized Exanthematous Pustulosis (AEGP). See section 2
- Serious, sudden allergic reaction with symptoms such as fever and blisters on the skin and peeling of the skin (toxic epidermal necrolysis). See section 2.
- Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS). Which consists of flu-like symptoms with a rash, fever, swollen glands and abnormal blood test results (including increased white blood cells (eosinophilia) and liver enzymes). See section 2.
- Symptoms of withdrawal may occur in newborn babies of mothers that have used Quetiapine Krka during their pregnancy.
- Stroke.
- Disorder of the heart muscle (cardiomyopathy).
- Inflammation of the heart muscle (myocarditis).
- Inflammation of blood vessels (vasculitis), often with skin rash with small red or purple bumps.

The class of medicines to which Quetiapine Krka belongs can cause heart rhythm problems, which can be serious and in severe cases may be fatal.

Some side effects are only seen when a blood test is taken. These include changes in the amount of certain fats (triglycerides and total cholesterol) or sugar in the blood, changes in the amount of thyroid hormones in your blood, increased liver enzymes, decreases in the number of certain types of blood cells, decrease in the amount of red blood cells, increased blood creatine phosphokinase (a substance in the muscles), decrease in the amount of sodium in the blood and increases in the amount of the hormone prolactin in the blood. Increases in the hormone prolactin could in rare cases lead to the following:
- Men and women to have swelling of breasts and unexpectedly produce breast milk.
- Women to have no monthly period or irregular periods.

Your doctor may ask you to have blood tests from time to time.

Additional side effects in children and adolescents
The same side effects that may occur in adults may also occur in children and adolescents.
The following side effects have been seen more often in children and adolescents or have not been seen in adults.

Very common: may affect more than 1 in 10 people
- Increase in the amount of a hormone called prolactin, in the blood. Increases in the hormone prolactin could in rare cases lead to the following:
  - boys and girls to have swelling of breasts and unexpectedly produce breast milk
  - girls to have no monthly period or irregular periods.
- Increased appetite.
- Vomiting.
- Abnormal muscle movements. These include difficulty starting muscle movements, shaking, feeling restless or muscle stiffness without pain.
- Increase in blood pressure.

Common: may affect up to 1 in 10 people
– Feeling weak, fainting (may lead to falls).
– Stuffy nose.
– Feeling irritated

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Quetiapine Krka

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton, container and blister after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

HDPE tablet container:
Shelf life after the first opening is 3 months.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Quetiapine Krka contains
- The active substance is quetiapine. Each tablet contains 25 mg, 100 mg, 200 mg or 300 mg quetiapine (as quetiapine hemifumarate).
- The other ingredients are lactose monohydrate; calcium hydrogen phosphate, dihydrate; microcrystalline cellulose; povidone K 25; sodium starch glycolate (type A); magnesium stearate (E572) in the tablet core and hypromellose; titanium dioxide (E171); macrogol 4000; yellow iron oxide (E172) (only in the 25 mg and 100 mg tablets) and red iron oxide (E172) (only in the 25 mg tablets) in the film-coating.
  See section 2 "Quetiapine Krka contains lactose and sodium".

What Quetiapine Krka looks like and contents of the pack
The 25 mg tablets are round (diameter 5 mm), pale red film-coated tablets with bevelled edge.
The 100 mg tablets are round (diameter 9 mm), yellow-brown film-coated tablets.
The 200 mg tablets are round (diameter 11 mm), white film-coated tablets.
The 300 mg tablets are capsule-shaped (length 18 mm, width 8 mm), white film-coated tablets.

Quetiapine Krka film-coated tablets are available in boxes of 6 (only the 25 mg tablets), 10, 20, 30, 30 x 1, 50, 60, 90, 98, 100, 100 x 1, 120 (only 300 mg tablets), 180 (only 300 mg tablets) or 240 (only 300 mg tablets) tablets in blisters and 250 tablets (only 100 mg and 200 mg tablets) in a container (HDPE).
Not all pack sizes may be marketed.

Marketing Authorisation Holder

KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia

Manufacturer
KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia
TAD Pharma GmbH, Heinz-Lohmann-Straße 5, 27472 Cuxhaven, Germany
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This medicine is authorised in the Member States of the European Economic Area under the following names:

Denmark	Quentiax
Ireland	Quetiapine Krka
Slovenia	Kvetiapin Krka

This leaflet was last revised in