

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S5**

QUETIAPINE 25 VIATRIS (film-coated tablets)

QUETIAPINE 100 VIATRIS (film-coated tablets)

QUETIAPINE 150 VIATRIS (film-coated tablets)

QUETIAPINE 200 VIATRIS (film-coated tablets)

QUETIAPINE 300 VIATRIS (film-coated tablets)

Quetiapine

Contains sugar: lactose monohydrate 4,5 mg (25 mg tablet); 18 mg (100 mg tablet); 27 mg (150 mg tablet); 36 mg (200 mg tablet); 54 mg (300 mg tablet)

Read all of this leaflet carefully before you start taking QUETIAPINE VIATRIS.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- QUETIAPINE VIATRIS has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What QUETIAPINE VIATRIS is and what it is used for
2. What you need to know before you take QUETIAPINE VIATRIS
3. How to take QUETIAPINE VIATRIS
4. Possible side effects
5. How to store QUETIAPINE VIATRIS
6. Contents of the pack and other information

1. What QUETIAPINE VIATRIS is and what it is used for

QUETIAPINE VIATRIS belongs to a group of medicines called antipsychotics. Antipsychotics improve the symptoms of certain types of mental illnesses.

QUETIAPINE VIATRIS is used to treat:

- 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).
- Mania phase in bipolar disorder where you may feel very excited, elated, agitated, enthusiastic or hyperactive or have poor judgment including being aggressive or disruptive.

2. What you need to know before you take QUETIAPINE VIATRIS

Do not take QUETIAPINE VIATRIS:

- If you are hypersensitive (allergic) to quetiapine or to any of the other ingredients in QUETIAPINE VIATRIS film-coated tablets (listed in section 6).
- If you are pregnant or breastfeeding.
- If you are a child or an adolescent under the age of 18 years.
- If you have advanced liver and renal function problems.
- If you are using any of the following medicines:
 - Protease inhibitors (for HIV infections);
 - Azole medicines (for fungal infections);
 - Medicines for infections such as erythromycin or clarithromycin;
 - Nefazodone (for depression).
- QUETIAPINE VIATRIS should not be taken by elderly patients with dementia (loss of brain function). This is because there is an increased risk of stroke, or in some cases the risk of death, in elderly patients with dementia.

Warnings and precautions

Take special care with QUETIAPINE VIATRIS.

Before you take QUETIAPINE VIATRIS tell your doctor:

- If you have diabetes mellitus or have a risk of getting diabetes mellitus. QUETIAPINE VIATRIS may increase blood sugar levels and worsen blood sugar control. Your doctor may check your blood sugar levels regularly while you are taking QUETIAPINE VIATRIS. Symptoms of high blood sugar (glucose) levels include drinking excessive amounts of water, urinating frequently, eating excessively and feeling weak.
- If you have any health problems (like heart problems or low blood pressure) or you have had a stroke.
- If you or a family member have a history of any problems with the way your heart beats or have a history of heart disease or heart problems or if you are taking any medicines that may have an impact on the way your heart beats.
- If you have any kidney or liver problems.
- If you or someone else in your family, have had a history of blood clots, as medicines like these have been associated with formation of blood clots.
- If 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).
- If you have a history of seizures (fits).
- If 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 "anticholinergics") that affect the way nerve cells function in order to treat certain medical conditions.
- If you have a history of alcohol or drug abuse.

Contact your doctor immediately or go to the nearest hospital if any of the following events happens to you (these are also described in the "Possible Side Effects" section below):

- If you feel "light-headed" and think you have low blood pressure.
- A combination of fever, very marked drowsiness, muscle stiffness, marked increase in blood pressure or heartbeats and reduced consciousness (a disorder called "neuroleptic malignant syndrome").

- Fits (seizures).
- Priapism (long-lasting and painful erection).
- Involuntary movements, mainly of your face or tongue (tardive dyskinesia).

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 VIATRIS 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.

Pancreatitis (inflammation of the pancreas) has been reported in some patients. Many of these patients also had factors which are known to be associated with pancreatitis such as increased triglyceride levels (a fatty substance in the blood), gallstones, and alcohol consumption.

Cardiomyopathy (weakening of the heart muscle) and myocarditis (inflammation of the heart) have been reported in some patients.

Thoughts of suicide and worsening of your depression or other mental illnesses

If you are depressed and/or have other mental illnesses, 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.

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 or have other mental illnesses and ask them to read this leaflet. You might ask them to tell you if they think your depression or mental illness is getting worse, or if they are worried about changes in your behaviour.

Severe cutaneous adverse reactions (SCARs)

Severe skin related adverse reactions including Stevens-Johnson Syndrome (SJS), Toxic Epidermal Necrolysis (TEN), Acute Generalised Exanthematous Pustulosis (AGEP), Erythema Multiforme (EM) and Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) which can be life threatening, have been reported with the use of this medicine.

These serious skin reactions may present with one or more combination of the following symptoms: widespread blistering (may be filled with pus) or peeling of the skin, flu-like symptoms, blood abnormalities (increase in a type of white blood cells), swollen glands (enlarged lymph nodes) or itchy skin rash with pink-red irregular spots.

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

Other medicines and QUETIAPINE VIATRIS

Always tell your health care provider if you are taking any other medicine (this includes complementary or traditional medicines).

These medicines should not be used with QUETIAPINE VIATRIS:

- Some medicines for human immunodeficiency virus (HIV) (protease inhibitors).
- Azole medicines (for fungal infections such as ketoconazole).
- Erythromycin or clarithromycin (for infections).
- Nefazodone (for depression).

Tell your doctor if you are taking any of the following medicines for:

- Anxiety or depression (such as centrally acting medicines, alcohol or an antipsychotic medicine called thioridazine).
- Epilepsy medicines (such as phenytoin or carbamazepine).
- Medicines that have an impact on the way your heart beats, for example medicines that can cause an imbalance in electrolytes (low levels of potassium or magnesium) such as diuretics (water pills) or certain antibiotics (medicines to treat infections).
- Medicines used for high blood pressure.
- Rifampicin (for tuberculosis).
- Barbiturates (for difficulty sleeping).
- Medicines that can cause constipation.
- Medicines (called anticholinergics) that affect the way nerve cells function in order to treat certain medical conditions.

Your doctor may consider a higher dose of QUETIAPINE VIATRIS while you are taking some of these medicines at the same time as QUETIAPINE VIATRIS.

Effect on Urine Drug Screens

If you are having a urine drug screen, taking QUETIAPINE VIATRIS may cause positive results for methadone or certain medicines for depression called tricyclic antidepressants (TCAs) when some test methods are used, even though you may not be taking methadone or TCAs. Confirmation of the results by more specific tests is recommended.

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

QUETIAPINE VIATRIS with food, drink and alcohol

QUETIAPINE VIATRIS may be taken with or without food.

If you drink alcohol, please mention this to your doctor before you start to take QUETIAPINE VIATRIS.

Pregnancy and breastfeeding

QUETIAPINE VIATRIS should not be used during pregnancy and breastfeeding.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Driving and using machines

QUETIAPINE VIATRIS may cause you to feel sleepy.

It is not always possible to predict to what extent QUETIAPINE VIATRIS may interfere with your daily activities. You should ensure that you do not engage in the driving a vehicle or use machines until you are aware of the measure to which QUETIAPINE VIATRIS affects you.

QUETIAPINE VIATRIS contains lactose

Patients with rare heredity problems of galactose intolerance, the Lapp lactose deficiency, or glucose-galactose malabsorption should not take this medicine.

3. How to take QUETIAPINE VIATRIS

Do not share medicines prescribed for you with any other person.

Always take QUETIAPINE VIATRIS exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Your doctor will decide on your starting dose and may gradually increase it. After this the total daily dose will usually be between 150 mg and 800 mg per day. This depends on your illness and will be determined by your doctor.

- The usual dose is twice a day.
- Swallow your tablets whole with a drink of water.
- Do not stop taking your tablets, even if you feel better, unless your doctor tells you to.

Elderly people:

If you are elderly your doctor will start your QUETIAPINE VIATRIS therapy at a lower dose.

Kidney and liver problems:

If you have kidney or liver disease your doctor will start your QUETIAPINE VIATRIS therapy at a lower dose.

Children and adolescents under 18 years:

QUETIAPINE VIATRIS should not be used by children and adolescents under the age of 18 years.

If you have the impression that the effect of QUETIAPINE VIATRIS is too strong or too weak, talk to your doctor or pharmacist.

If you take more QUETIAPINE VIATRIS than you should

If you take more than the recommended number of tablets, you are likely to feel drowsy, sleepy, rapid heartbeat and light-headed (low blood pressure).

In the event of overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take QUETIAPINE VIATRIS

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 dose.

If you stop taking QUETIAPINE VIATRIS

If you suddenly stop taking QUETIAPINE VIATRIS, you may be unable to sleep (insomnia), you may feel sick (nausea), or you may experience headache, diarrhoea, being sick (vomiting), dizziness or irritability.

Recurrence of your disease symptoms may also occur and symptoms such as involuntary movement disorder (restlessness), continuous muscle contractions, difficulty in movement or slow movement may occur.

Your doctor may suggest you reduce the dose gradually before stopping treatment to prevent these symptoms.

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

4. Possible side effects

QUETIAPINE VIATRIS can have side effects.

Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other health care provider for advice.

Frequent side effects:

- Dizziness.
- Feeling sleepy (this may go away as you continue taking your tablets).
- Headache.
- Rapid heartbeat.
- Dry mouth.
- Constipation.
- Indigestion.
- Abdominal pain.

- Diarrhoea.
- Feeling like your heart is pounding, racing or has skipped beats.
- Feeling weak.
- Swelling of arms and legs.
- Weight gain.
- Anxiety.
- Low blood pressure in standing position, which may result in dizziness or feeling faint.
- Increase in blood pressure.
- Shortness of breath.
- Vomiting (mainly in the elderly).
- Fever.
- Discontinuation symptoms (symptoms which occur when you stop taking QUETIAPINE VIATRIS) include not being able to sleep (insomnia), feeling sick (nausea), headache, diarrhoea, being sick (vomiting), dizziness and irritability.
- You may have abnormal muscle movements, including difficulty starting muscle movements, shaking, restlessness or muscle stiffness without pain.
- Blurred vision.
- Abnormal dreams and nightmares.
- Irritability.
- Feeling more hungry.
- Disturbance in speech and language.

Less frequent side effects:

- Hypersensitivity (allergic reactions that may include raised lumps (weals), swelling of all layers of the skin and swelling around the mouth or swelling of the throat, severe allergic reaction that may include difficulty in breathing, dizziness and collapse, itching and rash.
- Diabetes mellitus (or worsening of pre-existing diabetes).
- Fits (seizures).
- Restless legs (unpleasant sensations in the legs).

- Difficulty swallowing.
- Jaundice (yellowing of the skin and eyes), hepatitis (inflammation of the liver).
- Involuntary movements, mainly of your face or tongue (Tardive dyskinesia).
- Fainting (may lead to falls).
- Stuffy nose.
- A slower than normal heart rate which may occur when starting treatment and which may be associated with low blood pressure and fainting.
- 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.
- Difficulty in passing urine.
- Confusion.
- Combination of fever, very marked drowsiness, muscle stiffness, marked increase in blood pressure or heartbeats and reduced consciousness (a disorder called “neuroleptic malignant syndrome”).
- Men and women to have swelling of breasts and unexpectedly produce breast milk.
- Priapism (long-lasting and painful erection).
- Walking, talking, eating or other activities while you are asleep.
- Body temperature decreased (hypothermia).
- 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.
- Rhabdomyolysis (breakdown of muscle fibers and pain in muscles).
- Back pain.

Side effects that are of unknown frequency:

- Ear pain.
- Symptoms of withdrawal may occur in newborn babies of mothers that have used QUETIAPINE VIATRIS during their pregnancy.

- Combination of widespread rash, high body temperature, blood abnormalities (liver enzyme elevations, increase in a type of white blood cells sometimes seen in allergic reactions) and enlarged lymph nodes (a condition called “drug reaction with eosinophilia and systemic symptoms”) may occur.
- Rapid appearance of areas of red skin studded with small pustules (small blisters filled with white/yellow fluid called Acute Generalised Exanthematous Pustulosis (AGEP) and a severe form of skin rash with itchy pink-red irregular spots (a condition known as Erythema multiforme (EM) may occur.
- Inflammation of blood vessels (vasculitis), often with skin rash with small red or purple bumps.
- Urinary tract infection (bladder infection).
- Dry eyes, changes in the lens of the eye with long-term treatment.
- Chest pain.

The following side effects can also occur with QUETIAPINE VIATRIS, and they are seen when a blood test is taken:

- Decrease in the amount of white blood cells. These changes will normally disappear when stopping the treatment of QUETIAPINE VIATRIS.
- Decrease in the amount of red blood cells. These are the cells that transport oxygen throughout the body.
- Increase in the amount of eosinophils. These are a type of white blood cells, sometimes seen in allergic reactions.
- “Thrombocytopenia”, a decrease in platelets, which are cells that help you stop bleeding if you get a cut.
- Increase in the amount of liver enzymes. These changes will normally disappear when continuing the treatment of QUETIAPINE VIATRIS.
- Increase in the amount of fatty substances (lipid levels such as triglycerides and cholesterol) in the blood.
- Increase in the amount of “creatine phosphokinase”, a substance in the muscles.

- Increase in the amount of sugar (glucose) in the blood.
- Increase in the amount of the hormone prolactin in the blood. This may lead to:
 - Men and women to have swelling of breasts and unexpectedly, women to have no monthly period or irregular periods.
- Changes in the amount of thyroid hormones in your blood.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse.

You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

By reporting side effects, you can help provide more information on the safety of QUETIAPINE VIATRIS.

5. How to store QUETIAPINE VIATRIS

Store all medicines out of reach of children.

Store at or below 25 °C. Keep containers dry and tightly closed.

Do not store in bathrooms.

Do not use after the expiry date stated on the packaging.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What QUETIAPINE VIATRIS contains

The active substance is quetiapine.

QUETIAPINE 25 VIATRIS: Each film-coated tablet contains quetiapine fumarate corresponding to 25 mg quetiapine.

QUETIAPINE 100 VIATRIS: Each film-coated tablet contains quetiapine fumarate corresponding to 100 mg quetiapine.

QUETIAPINE 150 VIATRIS: Each film-coated tablet contains quetiapine fumarate corresponding to 150 mg quetiapine.

QUETIAPINE 200 VIATRIS: Each film-coated tablet contains quetiapine fumarate corresponding to 200 mg quetiapine.

QUETIAPINE 300 VIATRIS: Each film-coated tablet contains quetiapine fumarate corresponding to 300 mg quetiapine.

The other ingredients are: lactose monohydrate, microcrystalline cellulose, povidone, magnesium stearate, sodium starch glycolate, calcium hydrogen phosphate dihydrate, titanium dioxide, hydroxypropyl methylcellulose, macrogol, polysorbate 80 (150 mg, 200 mg, 300 mg tablets), iron oxide, yellow (100 mg, 150 mg tablets), iron oxide, red (25 mg tablets), iron oxide, black (150 mg tablets), talc (100 mg tablets).

What QUETIAPINE VIATRIS looks like and contents of the pack

QUETIAPINE 25 VIATRIS: Peach coloured, round, biconvex, film-coated tablet engraved 'Q' on one side.

QUETIAPINE 100 VIATRIS: Yellow, round, biconvex, film-coated tablet engraved 'Q' over '100' on one side.

QUETIAPINE 150 VIATRIS: Pale yellow, round, biconvex, film-coated tablet engraved 'Q' over '150' on one side.

QUETIAPINE 200 VIATRIS: White, round, biconvex, film-coated tablet engraved 'Q' over '200' on one side.

QUETIAPINE 300 VIATRIS: White, capsule-shaped, biconvex, film-coated tablet engraved 'Q' break line '300' on one side.

Packs of 1, 3, 6, 7, 10, 14, 20, 28, 30, 50, 56, 6, 84, 90, 98, 100, 250, 500, 1000 * tablets in PVC/PVDC aluminium foil blister strips and/or white HDPE bottles with white polyethylene caps.

*Not all pack sizes will be marketed.

Holder of Certificate of Registration

Viatri South Africa (Pty) Ltd

Viartis South Africa (Pty) Ltd
QUETIAPINE 25 VIATRIS; QUETIAPINE 100 VIATRIS; QUETIAPINE 150 VIATRIS;
QUETIAPINE 200 VIATRIS & QUETIAPINE 300 VIATRIS film-coated tablets
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4 Brewery Street

Isando

Kempton Park

Gauteng, 1601

Tel. no.: +27 11 451 1300

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QUETIAPINE 300 VIATRIS: 41/2.6.5/0955