PATIENT INFORMATION LEAFLET

- **Please read 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 or your pharmacist.**
- **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**

1) SCHEDULING STATUS: S5

2) PROPRIETARY NAME AND DOSAGE FORM:

QUETIAPINE 25 VIATRIS (film-coated tablet)

QUETIAPINE 100 VIATRIS (film-coated tablet)

QUETIAPINE 150 VIATRIS (film-coated tablet)

QUETIAPINE 200 VIATRIS (film-coated tablet)

QUETIAPINE 300 VIATRIS (film-coated tablet)

Quetiapine fumarate

3) WHAT QUETIAPINE VIATRIS CONTAINS:

Each film-coated tablet contains:

- Quetiapine fumarate corresponding to 25 mg, 100 mg, 150 mg, 200 mg or 300 mg quetiapine.
- Lactose monohydrate (sugar) corresponding to 4,5 mg, 18 mg, 27 mg, 36 mg and 54 mg respectively.

- The **other** ingredients are: microcrystalline cellulose, povidone, magnesium stearate, sodium starch glycolate, calcium hydrogen phosphate dehydrate and approved colourant; titanium dioxide.

4) WHAT QUETIAPINE VIATRIS IS USED FOR:

- **QUETIAPINE VIATRIS** contains a medicine called quetiapine. This belongs to a group of medicines called anti-psychotics. These medicines help with the effects of some types of mental illness such as:
- Schizophrenia.
- Bipolar mania.

5) BEFORE TAKING 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.
- If you are pregnant or breast-feeding If you are a child or an adolescent under the age of 18.
- 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
- **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.

Take special care with QUETIAPINE VIATRIS:

Before you take **QUETIAPINE VIATRIS** tell your doctor if:

- You have diabetes or have a risk of getting diabetes. **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.
- You have any health problems (like heart problems or low blood pressure) or you have had a stroke.
- 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.
- 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 have a history of seizures (fits).
- You develop signs and symptoms of tardive dyskinesia (uncontrollable movements, mainly of your face or tongue or slow or difficult movement of limbs (legs, arms, etc.)).
- **QUETIAPINE VIATRIS** must be discontinued and appropriate medical treatment given in case of neuroleptic malignant syndrome (abnormally high body temperature, abnormal muscle movements, which include difficulty starting muscle movements, shaking, feeling restless or muscle stiffness without pain).
- You have hereditary galactose intolerance as **QUETIAPINE VIATRIS** contains lactose.

  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.

Taking QUETIAPINE VIATRIS with food and drink:

QUETIAPINE VIATRIS may be taken with or without food.

Pregnancy and Breast-feeding:

QUETIAPINE VIATRIS should not be used during pregnancy and breast-feeding.

Driving and using machinery:

QUETIAPINE VIATRIS may cause you to feel sleepy. Make sure you know how you react to **QUETIAPINE VIATRIS** before you drive or use machines that require you to be alert.

Taking other medicines with QUETIAPINE VIATRIS:

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

- Medicines for anxiety or depression or strong pain killers.
- Antibacterials (e.g. macrolides such as erythromycin and clarithromycin) and anti-fungal medicines (e.g. ketoconazole, itraconazole).
- Medicines used for high blood pressure.
- Thioridazine (another anti-psychotic medicine).
- Rifampicin (for tuberculosis).
- Barbiturates (for epilepsy).
- Anti-epilepsy medicines (like carbamazepine or phenytoin).

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

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of QUETIAPINE VIATRIS with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional, for advice.

6) HOW TO TAKE QUETIAPINE VIATRIS:

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.

Do not share medicines prescribed for you with another person.

If you take more QUETIAPINE VIATRIS than you should:

If you take more **QUETIAPINE VIATRIS** than prescribed by your doctor, go to your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control center straight away. Take the **QUETIAPINE VIATRIS** tablets with you.

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.

7) SIDE EFFECTS:

QUETIAPINE VIATRIS can have side effects.

Frequent:

If any of the following happen, stop taking **QUETIAPINE VIATRIS** and contact your doctor or go to the nearest hospital immediately as you may need urgent medical attention:

- Blood disorders: 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.

- Dizziness, sleepiness, headache, anxiety, feeling faint, rapid heartbeat, low blood pressure when standing up from lying down or sitting, increase in blood pressure
- Stuffy nose, dry mouth, indigestion or constipation, abdominal pain, diarrhoea, feeling weak, swelling of arms, hands or legs, putting on weight.

Less Frequent:

- 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)
- Seizures.
- Tardive dyskinesia (uncontrollable movements, mainly of your face [~~or~~] and tongue).
- Dry eyes, changes in the lens of the eye with long-term treatment.
- Ear pain.
- Jaundice (yellowing of the skin and eyes), hepatitis (inflammation of the liver)
- Severe skin rash, muscle pain back pain, urinary tract infection.
- Priapism (a long-lasting and painful erection).
- Chest pain.

Some side effects are only seen when a blood test is taken (these include increase in the amount of blood fats, liver enzymes or sugar in the blood, decreases in the number of certain types of blood cells.

Neuroleptic malignant syndrome (a group of symptoms characterized by a raised body temperature (fever), altered mental status, muscle stiffness and spells of dizziness, shortness of breath, a racing heartbeat, fatigue and melancholy (depression).

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 professional for advice.

8) STORAGE AND DISPOSAL OF QUETIAPINE VIATRIS:

Store at or below 25 ^{O}C. Keep containers dry and tightly closed.

Keep all medicines out of the reach and sight of children.

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).

9) PRESENTATION:

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.

10) IDENTIFICATION OF QUETIAPINE VIATRIS:

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.

11) REGISTRATION NUMBERS:

QUETIAPINE 25 VIATRIS: 41/2.6.5/0951

QUETIAPINE 100 VIATRIS: 41/2.6.5/0952

QUETIAPINE 150 VIATRIS: 41/2.6.5/0953

QUETIAPINE 200 VIATRIS: 41/2.6.5/0954

QUETIAPINE 300 VIATRIS: 41/2.6.5/0955

12) NAME AND THE BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE:

Viatris South Africa (Pty) Ltd

4 Brewery Street,

Isando

Johannesburg,

1609

13) DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET:

16 August 2011