PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S5

QUETIAPINE 25 UNICORN

Each film coated tablet contains 25 mg of quetiapine.

Contains sugar (lactose monohydrate 10,7 mg/tablet).

QUETIAPINE 100 UNICORN

Each film coated tablet contains 100 mg of quetiapine.

Contains sugar (lactose monohydrate 42,9 mg/tablet).

QUETIAPINE 200 UNICORN

Each film coated tablet contains 200 mg of quetiapine.

Contains sugar (lactose monohydrate 85,7 mg/tablet).

QUETIAPINE 300 UNICORN

Each film coated tablet contains 300 mg of quetiapine.

Contains sugar (lactose monohydrate 128,6 mg/tablet).

Read all of this leaflet carefully before you start taking QUETIAPINE UNICORN

- 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 UNICORN** 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 UNICORN** is and what it is used for

2. What you need to know before you take **QUETIAPINE UNICORN**

3. How to take **QUETIAPINE UNICORN**

4. Possible side effects

5. How to store **QUETIAPINE UNICORN**

6. Contents of the pack and other information

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

QUETIAPINE UNICORN contains quetiapine. This belongs to a group of medicines called anti-psychotics. **QUETIAPINE UNICORN** can be used to treat:

- Schizophrenia: where you may hear or feel things that do not there, believe things that are not true or feel unusually suspicious, anxious, confused, guilty, tense or depressed.
- Manic episodes associated with a 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 UNICORN

Do not take QUETIAPINE UNICORN

- If you are hypersensitive (allergic) to quetiapine or any of the other ingredients of **QUETIAPINE UNICORN** (listed in section 6).
- If you are pregnant or breastfeeding.
- If you are a child or adolescent, safety has not been demonstrated in persons under the age of 18.
- If you have advanced liver and kidney diseases.
- if you are taking any of the following medicines:
    - Certain HIV medicines
    - Azole medicines (for fungal infections)
    - Erythromycin or clarithromycin (for infections)
    - Nefazodone (for depression)

Take special care with QUETIAPINE UNICORN:

Talk to your doctor or pharmacist before taking **QUETIAPINE UNICORN**

- 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 affect the way your heart beats.
- If you have low blood pressure.
- If you have had a stroke, especially if you are elderly.
- If you have liver problems.
- If you have ever had a fit (seizure).
- If 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 UNICORN.**
- 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 are an elderly person with dementia (loss of brain functions). If you are, **QUETIAPINE UNICORN** should not be taken because the group of medicines that **QUETIAPINE UNICORN** belongs to may increase the risk of stroke or in some cases the risk of death, in elderly people with dementia.
- If you are an elderly person with Parkinson's disease.
- If 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.
- if you have or have had a condition where you stop breathing for short periods during sleep (sleep apnoea) and are taking medicines that slow down the normal activity of the brain.
- if you have or have had a condition where you cannot completely empty your bladder, have an enlarged prostate, a blockage in your intestines, or increased pressure inside

your eye. These conditions are sometimes caused by medicines (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.

Tell your doctor immediately if you experience any of the following after taking **QUETIAPINE UNICORN**

- A combination of fever, severe muscle stiffness, sweating or a lowered level of consciousness. These are signs of neuroleptic malignant syndrome and 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).

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 UNICORN** to be stopped and/or treatment to be given.
- Constipation along with 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. These may be increased when first starting treatment, since these medicines take time to work (usually about two weeks). These thoughts may also be increased if you suddenly stop taking your medication. If you have these thoughts 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.

- **Drug Rash with Eosinophilia and Systemic Symptoms (DRESS)**

  Stop using **QUETIAPINE UNICORN** if you develop the following and contact your doctor or seek medical attention immediately:

  Widespread rash, high body temperature, increase in liver enzyme, blood abnormalities (eosinophilia) and enlarged lymph nodes.

- **Weight gain**

  You and your doctor should check your weight regularly as weight gain has been seen in patients taking **QUETIAPINE UNICORN.**

- **Children and adolescents**

  QUETIAPINE UNICORN is not for use in children and adolescents below 18 years of age.

Other medicines and QUETIAPINE UNICORN

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

Do not take **QUETIAPINE UNICORN** if you are taking any of the following medicines:

- Certain HIV medicines
- Azole medicines used for fungal infections.
- Erythromycin or clarithromycin used for infections.
- Nefazodone used for depression.

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

- Epilepsy medicines (phenytoin or carbamazepine).
- High blood pressure medicines.
- Barbiturates (for sleeping difficulties).
- Thioridazine or lithium (other anti-psychotic medicines).
- 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 that can cause constipation.
- Medicines (called anticholinergics) that affect the way nerve cells work.

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

QUETIAPINE UNICORN with food, drink and alcohol

The tablets may be taken with or without food and a glass of water.

Avoid using alcohol during your treatment.

Do not drink grapefruit juice while you are taking **QUETIAPINE UNICORN** as it can affect the way the medicine works.

Pregnancy, breastfeeding and fertility

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.

Pregnancy

You should not take **QUETIAPINE UNICORN** during pregnancy (see 'Do not take **QUETIAPINE UNICORN**').

Breastfeeding

You should not breastfeed your baby while you are taking **QUETIAPINE UNICORN** (see 'Do not take **QUETIAPINE UNICORN').**

Driving and using machines

QUETIAPINE UNICORN may impair your ability to drive and use machinery as it may make you feel sleepy.

It is not always possible to predict to what extent **QUETIAPINE UNICORN** may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which **QUETIAPINE UNICORN** affects them.

Important information about some of the ingredients of QUETIAPINE UNICORN

QUETIAPINE UNICORN contains lactose.
Patients with the rare hereditary conditions of lactose/fructose or galactose intolerance should not take **QUETIAPINE UNICORN.**

Effect on Urine Drug Screens

If you are having a urine drug screen, taking **QUETIAPINE UNICORN** may cause positive results for methadone or certain medicines for depression called tricyclic antidepressants when some test methods are used, even though you may not be taking these. If this happens, a more specific test should be performed.

3. How to take QUETIAPINE UNICORN

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

Always take **QUETIAPINE UNICORN** exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is orally twice daily in two divided doses, with or without food.

Do not drink grapefruit juice while you are taking **QUETIAPINE UNICORN** as it can affect the way the medicine works.

Adults:

You doctor will determine your treatment dose and changes in the dose according to your response and tolerability to the treatment.

Elderly:

QUETIAPINE UNICORN treatment will be with reduced initial and target dosages, and slower dosages changes may be required compared to younger adult patients.

Kidney and liver diseases:

If you have a kidney of liver disease, your **QUETIAPINE UNICORN** treatment will be with reduced initial and target dosages, and slower dosages changes may be required compared to younger adult patients.

Your doctor may perform certain urinary, blood tests or eye examinations to ensure the effectiveness and safe use of **QUETIAPINE UNICORN** prior and during your treatment.

Your doctor will tell you how long your treatment with **QUETIAPINE UNICORN** will last. If you have the impression that the effect of **QUETIAPINE UNICORN** is too strong or too weak, tell your doctor or pharmacist.

If you take more QUETIAPINE UNICORN than you should

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

If you forget to take QUETIAPINE UNICORN

If you have missed a dose by only a few hours, take the missed dose as soon as you remember. If it is almost time for your next dose, skip the missed dose and take **QUETIAPINE UNICORN** at the next regularly scheduled time. Do not take a double dose to make up for the forgotten individual doses.

If you stop taking QUETIAPINE UNICORN

If you suddenly stop taking **QUETIAPINE UNICORN**, you may be unable to sleep (insomnia), or you may feel nauseous, or you may experience headache, diarrhoea, vomiting, dizziness or irritability. Your doctor may suggest lowering the dose gradually before stopping treatment.

4. Possible side effects

QUETIAPINE UNICORN can have side effects.

Not all side effects reported for **QUETIAPINE UNICORN** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **QUETIAPINE UNICORN**, please consult your health care provider for advice.

The class of medicines to which **QUETIAPINE UNICORN** 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. Such as changes in the amount of certain fats (triglycerides and total cholesterol) or sugar in the blood, changes in the amount of thyroid hormones,, 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. Prolactin increase may cause men and women to have swelling of the breasts and unexpectedly produce breast milk. Women may not have their monthly period or have irregular periods.

If any of the following happens, stop taking **QUETIAPINE UNICORN** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting

These are all very serious side effects. If you have them, you may have had a serious reaction to **QUETIAPINE UNICORN**. You may need urgent medical attention or hospitalisation.

Frequent side effects:

- Dizziness (may lead to falls), headache, dry mouth.
- Feeling sleepy (this may go away with time, as you keep taking **QUETIAPINE UNICORN**) (may lead to falls).
- Withdrawal symptoms if you stop taking **QUETIAPINE UNICORN** such as not being able to sleep (insomnia), nausea, headache, diarrhoea, vomiting, dizziness and irritability.
- Weight gain
- 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).
- Rapid heartbeat.
- Feeling like your heart is pounding, racing or skipping 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 than usual.
- Feeling irritated.
- Disturbance in speech and language.
- Thoughts of suicide and worsening of your depression.
- Shortness of breath.
- Vomiting (mainly in the elderly).
- Fever.

Less frequent side effects:

- Fits or seizures.
- Allergic reactions that may include raised lumps (wheals), swelling of the skin and swelling around the mouth.
- Unpleasant sensations in the legs (restless legs syndrome).
- Difficulty in swallowing.
- Uncontrollable movements, mainly of your face and tongue.
- Sexual abnormality.
- Diabetes, or worsening of pre-existing 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.
- A combination of 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.
- 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 breathing difficulties. If you notice any of these symptoms seek medical attention immediately.
- Walking, talking, eating or other activities while you are asleep.
- Decreased body temperature (hypothermia).
- Inflammation of the pancreas.
- A condition called metabolic syndrome, where you 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 (agranulocytosis).
- Bowel obstruction.

- Increased blood creatine phosphokinase (a substance from the muscles).
- Severe rash, blisters, or red patches on the skin.
- A severe allergic reaction which may cause difficulty in breathing or shock.
- Rapid swelling of the skin, usually around the eyes, lips and throat.
- A serious blistering condition of the skin, mouth, eyes and genitals (Stevens-Johnson syndrome).
- Inappropriate secretion of a hormone that controls urine volume.
- Breakdown of muscle fibers and pain in muscles.
- Skin rash with uneven red spots (erythema multiforme).
- Serious, sudden allergic reaction with symptoms such as fever and blisters on the skin and peeling of the skin (toxic epidermal necrolysis).
- Stroke.

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 or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found on-line under SAHPRAs publications: https://www.sahpra.org.za/Publications/Index/8. Side effects must also be reported to Unicorn Pharmaceuticals (Pty) Ltd to vigilance@unicornpharma.co.za.
By reporting side effects, you can help provide more information on the safety of **QUETIAPINE UNICORN.**

5. How to store QUETIAPINE UNICORN

Store all medicines out of reach of children.

- Store at or below 25 ºC.
- Keep blisters in outer carton until required for use.
- Do not use the tablets after the expiry date printed on the container.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What QUETIAPINE UNICORN contains

- The active substance is:

  quetiapine
- The other ingredients are:

  dibasic calcium phosphate dehydrate, microcrystalline cellulose, lactose monohydrate, sodium starch glycolate, povidone and magnesium stearate.

  Film coating

  QUETIAPINE 25 UNICORN : Opadry orange which contains hypromellose, titanium dioxide, macrogol, iron oxide yellow, iron oxide red.

  QUETIAPINE 100 UNICORN: Opadry yellow which contains hypromellose, titanium dioxide, macrogol, iron oxide yellow.

  QUETIAPINE 200 UNICORN and QUETIAPINE 300 UNICORN: Opadry white which contains hypromellose, titanium dioxide, macrogol.

What QUETIAPINE UNICORN looks like and contents of the pack

QUETIAPINE 25 UNICORN: Peach coloured, round shaped, biconvex, film coated tablets, debossed with “J” on one side and “25” on the other side.

QUETIAPINE 100 UNICORN: Yellow coloured, round shaped, biconvex, film coated tablets, debossed with “J” on one side and “100” on the other side.

QUETIAPINE 200 UNICORN: White coloured, round shaped, biconvex, film coated tablets, debossed with “J” on one side and “200” on other side.

QUETIAPINE 300 UNICORN: White coloured, capsule shaped, biconvex, film coated tablets, debossed with “J” on one side and “300” on other side.

QUETIAPINE UNICORN tablets are packed into clear white opaque / silver aluminium blisters strips, containing 10 tablets each.

QUETIAPINE 25 UNICORN: Pack sizes of 100 tablets (10 blister strips of 10 tablets).

QUETIAPINE 100 UNICORN: Pack sizes of 90 tablets (9 blister strips of 10 tablets).

QUETIAPINE 200 UNICORN: Pack sizes of 60 tablets (6 blister strips of 10 tablets).

QUETIAPINE 300 UNICORN: Pack sizes of 60 tablets (6 blister strips of 10 tablets).

Holder of Certificate of Registration

Unicorn Pharmaceuticals (Pty) Ltd

Corner of Searle & Pontac Streets,

Cape Town,

South Africa, 8001

enquiries@unicornpharma.co.za

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