Patient information leaflet for QUETIAPINE BIOTECH 25, 100, 200, 300

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S5

QUETIAPINE BIOTECH 25, 100, 200, 300, film-coated tablets

Quetiapine

Contains sugar (QUETIAPINE BIOTECH 25 contains 15,371 mg, QUETIAPINE BIOTECH 100 contains 61,484 mg, QUETIAPINE BIOTECH 200 contains 122,968 mg and QUETIAPINE BIOTECH 300 contains 184,452 mg lactose monohydrate per film-coated tablet).

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- QUETIAPINE BIOTECH 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 BIOTECH is and what it is used for
2. What you need to know before you take QUETIAPINE BIOTECH
3. How to take QUETIAPINE BIOTECH
4. Possible side effects
5. How to store QUETIAPINE BIOTECH

6. Contents of the pack and other information.

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

QUETIAPINE BIOTECH belongs to a group of medicines called antipsychotics. It can be used to treat schizophrenia (a condition where you may hear or feel things that are not there, believe things that are not true or feel unusually confused) and bipolar mania (depression).

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

Do not take QUETIAPINE BIOTECH:

- If you are hypersensitive (allergic) to quetiapine or any of the other ingredients of QUETIAPINE BIOTECH (listed in section 6).
- If you are a child or adolescent under the age of 18 years.
- If you are pregnant or breastfeeding.
- If your liver or kidney function is severely impaired.
- If you are an elderly person with dementia (memory loss).
- If you are taking any of the following medicines:
  - some medicines for HIV (used in the treatment of HIV (human immunodeficiency virus) and AIDS (acquired immune deficiency syndrome))
  - azole medicines (used to treat fungal infections)
  - erythromycin, clarithromycin (used to treat bacterial infections)
  - nefazodone (used to treat depression).

Warnings and precautions

Take special care with QUETIAPINE BIOTECH:

- If you have thoughts of suicide and if your depression is getting worse. These may be increased when first starting treatment with QUETIAPINE BIOTECH. If you have thoughts of harming or killing yourself at any time, contact your doctor or go to a hospital immediately.
- If you gain weight or if you blood sugar levels increase while taking QUETIAPINE BIOTECH,

consult your doctor. You and your doctor should check your weight regularly.

- If you develop an unpleasant restlessness and need to move often accompanied by an inability to sit or stand still while taking QUETIAPINE BIOTECH, consult your doctor.
- If you have high blood sugar or diabetes, or have a risk of getting diabetes, your doctor may check your blood sugar levels while you are taking QUETIAPINE BIOTECH.
- If you are an elderly person with dementia (memory loss). QUETIAPINE BIOTECH should not be taken because the group of medicines that QUETIAPINE BIOTECH belongs to may increase the risk of stroke, or in some cases the risk of death.
- If you are an elderly person with Parkinson's disease/parkinsonism (a condition with the following symptoms: trembling in hands, arms, legs, jaw or head, stiffness of the limbs, impaired balance and coordination).
- If you have a history of seizures (fits).
- If you have any heart disease or low blood pressure.
- If you have had a stroke.
- If you know that you have had low levels of white blood cells in the past.
- If you are suffering from Alzheimer's disease.
- If you have a history of abusing substances/medicines or alcohol.
- If you or someone else in your family has a history of blood clots.
- If severe cutaneous adverse reactions (SCARs) develop while taking QUETIAPINE BIOTECH, stop taking QUETIAPINE BIOTECH and consult your doctor immediately. These reactions can be life-threatening. 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).

- If 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”).
- 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 conditions.
- QUETIAPINE BIOTECH may increase your cholesterol levels. Your doctor might monitor your cholesterol levels while you are taking QUETIAPINE BIOTECH.
- If symptoms such as yellowing of the skin and eyes, dark urine, and tiredness develop while taking QUETIAPINE BIOTECH. These may be symptoms of liver problems.
- If you develop constipation or persistent abdominal pain while taking QUETIAPINE BIOTECH. Consult your doctor. These symptoms may indicate a blockage of your bowel.

Tell your doctor immediately if you experience:

- 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 feeling very drowsy. This could increase the risk of accidental injury (fall) in elderly patients.
- Fits (seizures).
- A long lasting and painful erection (priapism).

Children and adolescents

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

Other medicines and QUETIAPINE BIOTECH

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

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

- ketoconazole, itraconazole or other antifungal medicines
- phenytoin, carbamazepine, sodium valproate (antiepileptic medicine)
- lithium (medicine used to treat some types of depression)
- imipramine, fluoxetine (medicines used to treat depression)
- lorazepam (medicine for anxiety)
- rifampicin (medicine for TB)
- alcohol
- thioridazine (medicine used for psychosis or anxiety)
- antihypertensive medicine (medicine that lowers your blood pressure)
- medicines that affect the heart, e.g. medicines that can cause an imbalance in some of the chemicals in your blood such as diuretics (water pills) or certain antibiotics
- medicines called anti-cholinergics they affect the way nerve cells function to treat certain conditions.

QUETIAPINE BIOTECH with food, drink and alcohol

QUETIAPINE BIOTECH can be taken with or without food.

Do not drink grapefruit juice while taking QUETIAPINE BIOTECH. Grapefruit juice can affect the way QUETIAPINE BIOTECH works.

Drinking alcohol while taking QUETIAPINE BIOTECH may make you sleepy. Be careful how much alcohol you drink.

Pregnancy, breastfeeding and fertility

QUETIAPINE BIOTECH should not be used by pregnant women or women breastfeeding their infants.

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 QUETIAPINE BIOTECH.

Driving and using machines

QUETIAPINE BIOTECH can cause dizziness, fits and fainting. Please make sure you know how QUETIAPINE BIOTECH affects you prior to driving a vehicle or operating machinery.

QUETIAPINE BIOTECH contains lactose monohydrate

QUETIAPINE BIOTECH contains lactose monohydrate 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 QUETIAPINE BIOTECH.

3. How to take QUETIAPINE BIOTECH

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

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

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

The dosage will be different for each patient and will be adjusted according to your clinical condition.

QUETIAPINE BIOTECH should be used twice daily, with or without food.

Adult treatment of schizophrenia:

For the treatment of schizophrenia the total daily dose for the first 4 days of therapy is 50 mg (Day 1), 100 mg (Day 2), 200 mg (Day 3) and 300 mg (Day 4). From Day 4 onwards, the dose should be increased by your healthcare professional to the effective dose range of 300 – 450 mg/day.

Further dosage adjustments up to 750 mg per day will be considered by your healthcare professional.

Adult treatment of manic episodes associated with bipolar disorder:

For the treatment of manic episodes associated with bipolar disorder, the total daily dose for the first 4 days of therapy is 100 mg (Day 1), 200 mg (Day 2), 300 mg (Day 3) and 400 mg (Day 4). Further dosage adjustments up to 800 mg/day by Day 6 in increments of no greater than 200 mg/day, will be considered by your healthcare professional.

Elderly patients:

Your dose should be started on QUETIAPINE BIOTECH 25 mg/day. Your healthcare professional will adjust the dose if needed.

Kidney and liver impairment:

Your dose should be started on QUETIAPINE BIOTECH 25 mg/day. Your healthcare professional will adjust the dose if needed.

If you take more QUETIAPINE BIOTECH than you should

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

If you forget to take QUETIAPINE BIOTECH

If you forget to take a dose, take it as soon as you remember. Do not take a double or larger dose to make up for the forgotten individual doses. Continue to take the next tablet at the usual time.

If you stop taking QUETIAPINE BIOTECH

QUETIAPINE BIOTECH should be withdrawn over a period of at least one to two weeks. Acute withdrawal symptoms such as inability to sleep, nausea (feeling sick), headache, diarrhoea,

vomiting (being sick), dizziness and irritability may occur when QUETIAPINE BIOTECH treatment is stopped abruptly.

4. Possible side effects

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

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

- Swelling of the hands, feet, ankles, face, lips, 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 BIOTECH. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

Frequent side effects:

- Frequent infections such as fever, severe chills, sore throat or mouth ulcers.
- Shortness of breath, weakness, dizziness, headache.
- Skin infections, mouth ulcers, swollen gums, fever.
- Thoughts about harming or killing yourself.

Less frequent side effects:

- Bleeding or bruising more easily than normal.

- Seizures or fits.
- If you develop a rare and unpredictable reaction to the active ingredient, quetiapine, known as neuroleptic malignant syndrome (NMS). The syndrome is characterised by fever, muscular rigidity and altered mental status.
- Restlessness of the legs.
- Changes in the way your heart beats, for example, if you notice it beating faster, slower or skipping beats.
- Heart attack.
- Unexplained death.
- Yellow pigmentation of the skin and whites of the eyes.
- If either of your lower legs (calve muscles) become swollen or red and painful, you might have a blood clot.
- Painful, blistering or peeling skin rash, such as Stevens-Johnson syndrome or toxic epidermal necrolysis.
- Difficulty in passing urine.

Frequency unknown:

- Chest pain.
- Sudden numbness or weakness in the face, arm, or leg especially on one side of the body.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Dizziness and/or fainting.
- Dry mouth.
- Constipation.
- Stomach pain.
- Irritability.
- Light-headedness or numbness/tingling after standing up from a seated position (orthostatic

hypotension).

- Ear pain.
- Runny nose.
- Weight gain.
- Headache.
- An unpleasant sensation of inner restlessness; absence, poverty or loss of control of voluntary muscle movements; reduced ability of a muscle to stretch; neck rigidity and tremor.
- Abnormal dreams and nightmares.
- Vomiting.
- A lack or loss of strength.
- Increased blood sugar.
- Increased cholesterol.
- Dry eyes or blurred vision.
- Increased appetite.

Less frequent side effects:

- Anaemia (fatigue, loss of energy, pale skin, cramps in your legs, difficulty with concentration).
- Sexual dysfunction.
- Menstrual disorders.
- Swelling of breasts.
- Sleep disturbances.
- Back pain.
- Long-lasting and painful erection.
- Muscle aches and pain, stiffness and muscle weakness (rhabdomyolysis).
- Sleep walking and sleep talking.
- Anxiety.
- Runny stools.
- Hepatitis.
- Decreased appetite.

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. You can also report side effects to SAHPRA via the “Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of QUETIAPINE BIOTECH.

5. How to store QUETIAPINE BIOTECH

- Store at or below 25 °C.
- Keep blister strips in the outer carton until required for use.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use the tablets after the expiry date printed on the container or blister strip.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What QUETIAPINE BIOTECH contains

The active substance is quetiapine.

QUETIAPINE BIOTECH 25: Each film-coated tablet contains 25 mg of quetiapine free base.

QUETIAPINE BIOTECH 100: Each film-coated tablet contains 100 mg of quetiapine free base.

QUETIAPINE BIOTECH 200: Each film-coated tablet contains 200 mg of quetiapine free base.

QUETIAPINE BIOTECH 300: Each film-coated tablet contains 300 mg of quetiapine free base.

The inactive ingredients are colloidal anhydrous silica, glycerol dibehenate, hypromellose, lactose monohydrate, macrogol 4000, magnesium stearate, microcrystalline cellulose, povidone K-25, sodium starch glycolate type A, red iron oxide (colourant for 25 mg strength), titanium dioxide,

yellow iron oxide (colourant for 100 mg strength).

What QUETIAPINE BIOTECH looks like and contents of the pack

QUETIAPINE BIOTECH 25: Round biconvex pink film-coated tablet.

QUETIAPINE BIOTECH 100: Round biconvex yellow film-coated tablet, scored on one side.

QUETIAPINE BIOTECH 200: Round biconvex white film-coated tablet, scored on one side.

QUETIAPINE BIOTECH 300: Oblong biconvex white film-coated tablet, scored on one side.

30; 60; 90 or 100 tablets are packed in polyamide/aluminium/PVC blister strips or PVC/aluminium and aluminium blister strips. Each contains ten tablets. The blister strips are packed in an outer carton.

Not all pack sizes may be marketed.

Holder of certificate of registration

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