APPROVED PATIENT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S5

QUERO XR 50 mg film coated tablet

QUERO XR 150 mg film coated tablet

QUERO XR 200 mg film coated tablet

QUERO XR 300 mg film coated tablet

QUERO XR 400 mg film coated tablet

Quetiapine Fumarate

QUERO XR contains sugar (lactose anhydrous 14,21 mg, 42,63 mg, 56,84 mg, 85,26 and 113,68 mg per tablet, respectively)

Read all of this leaflet carefully before you start taking QUERO XR

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist, nurse or other healthcare provider.
- QUERO XR 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 QUERO XR is and what it is used for

QUERO XR contains quetiapine fumarate, one of a group of medicines called antipsychotics.

QUERO XR is used in the treatment of:

- 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
- depressive episodes associated with bipolar disorder: where you feel sad. You may find that you feel depressed, guilty, lack energy, lose your appetite or can't sleep
- manic episodes associated with bipolar disorder: where you may feel very excited, elated, agitated, enthusiastic or hyperactive or have poor judgment including being aggressive or disruptive

- preventing recurrence in the maintenance treatment of bipolar disorder (manic mixed or depressive episodes) as monotherapy or in combination with mood stabilisers
- major Depressive Disorder (MDD): where you are persistently experience a depressed mood or loss of interest in activities, causing significant impairment in daily life
- preventing relapse in stable major depressive disorder patients who have been maintained on QUERO XR.

2. What you need to know before you take QUERO XR

Do not take QUERO XR:

- if you are hypersensitive (allergic) to quetiapine or any of the other ingredients of QUERO XR (see 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 pregnant or breastfeeding your baby
- if you are child (10 – 12 years) or adolescent (13 – 17 years), as safety and efficacy have not been established

- if you suffer from advanced liver or renal dysfunction, as safety has not been demonstrated.

Warnings and precautions

Take special care with QUERO XR:

- if you have diabetes, or are have a risk of getting diabetes (e.g. obesity, family history of diabetes), your doctor may check your blood sugar levels while you are taking QUERO XR
- if you have previously had thoughts about killing yourself, or have attempted suicide, 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 QUERO XR (see section below)
- if you have had low levels of white blood cells in the past (which may or may not have been caused by other medicines), and experience flu-like symptoms including fever, sore throat or any other infection, as this could be a result of a very low white blood cell count and may require QUERO XR to be stopped
- if you have a problem with your cholesterol levels
- when you start and during therapy with QUERO XR, your doctor will perform test to check for changes in your weight, blood glucose levels and cholesterol levels
- if you have low blood pressure, as QUERO XR lowers blood pressure and causes dizziness which can increase the risk of accidental injury (fall) in elderly patients

- if you are prone to, or have ever had, fits (seizures)
- if you begin to experience involuntary movements of the face and jaw whilst taking QUERO XR
- if you develop akathisia (with symptoms such as distressing restlessness and the need to move often, accompanied by the inability to sit down or standstill) during the initial stages of treatment with QUERO XR
- if you begin to experience a combination of symptoms such as fever, altered mental status, muscle rigidity, increased or decreased sweating dizziness, fainting or a lowered level of consciousness (a disorder called neuroleptic malignant syndrome), as immediate medical treatment may be needed
- if you or someone in your family, have or have had any heart problems such as a very fast heart beat or prolonged QT on an ECG (heart tracing), weakening of the heart muscle or inflammation of the heart or if you are taking any medicines that may have an effect on the way your heart beats
- if you abruptly stop treatment as you may experience unwanted side effects such as insomnia, nausea, headache, diarrhoea, vomiting, dizziness, and irritability
- if you experience extreme sleepiness in the beginning stages of treatment with QUERO XR, your doctor may wish to see you more frequently than is normal
- 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 are at risk of catching pneumonia, since QUERO XR may affect swallowing or breathing
- 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 "anti-cholinergics") that affect the way nerve cells function in order to treat certain medical conditions
- if you suffer from 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
- if you or someone else in your family has a history of blood clots, as quetiapine, as contained in QUERO XR, has been associated with formation of blood clots
- if you have had or have gall stones
- if you have a history of alcohol or drug abuse
- if you experience liver problems
- if you have a weight problem or your weight increases during treatment
- if you are an elderly person with Parkinson's Disease/parkinsonism
- if you are an elderly person with dementia (loss of brain function), QUERO XR should not be taken because this group of medicines may increase the risk of stroke, or in some cases the risk of death

- if you have depression or other conditions that are treated with antidepressants. The use of these medicines together with QUERO XR can lead to serotonin syndrome, a potentially life-threatening condition (see Other medicines and QUERO XR).

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) consist of flu-like symptoms with a rash, fever, swollen glands, and abnormal blood test results (including increased white blood cells (eosinophilia) and liverenzymes).

Stop taking QUERO XR if you develop these symptoms and contact your doctor or seek medical attention immediately.

Children and adolescents

Children and adolescents under the age of 18 years you should not take QUERO XR.

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 2 weeks but sometimes longer.

You may be more likely to think like this if:

- you have previously had thoughts about killing or harming yourself.
- you are a child, teenager or young adult. Information from clinical trials has shown an increased risk of suicidal thoughts and/or suicidal behaviour in children, teenagers, or young adults aged less than 25 years with psychiatric conditions who were treated with an antidepressant.

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.

Other medicines and QUERO XR

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

- ketoconazole (for fungal infections) affects the way QUERO XR works

- anti-depressants. These medicines may interact with QUERO XR 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.
- carbamazepine and phenytoin (used in the treatment of epilepsy), as taking these medicines affect the way QUERO XR works and doses may need to be adjusted
- medicines (called anti-cholinergics) that affect the way nerve cells function in order to manage and treat a wide range of diseases such as such as nausea, irritable bowel syndrome, and eye problems
- certain antibiotics (erythromycin or clarithromycin), antifungal medication (e.g. fluconazole) or medicines used to treat HIV/aids and hepatitis should not be taken with QUERO XR (see Do not take QUERO XR)
- barbiturates (used for sleeping difficulty) or rifampicin (for tuberculosis), as your dose of QUERO XR may need to be adjusted
- 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 to treat infections)

- urine screening tests whilst taking QUERO XR may cause positive results for methadone or tricyclic antidepressants, even though you may not be taking any other medicines. Any result will need to be re-confirmed by a more specific test.

QUERO XR with food, drink and alcohol

QUERO XR can be taken with or without food.

Do not consume grapefruit juice while you are taking QUERO XR, since grapefruit juice can affect the way your medicine works.

Be careful how much alcohol you drink. This is because the combined effect of QUERO XR and alcohol can make you sleepy.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before using QUERO XR.

You should not use this medicine if you are pregnant or breastfeeding your baby.

The effects of quetiapine on human fertility have not been assessed.

Driving and using machines

QUERO XR may make your feel tired, sleepy or dizzy and affect your ability to drive and use machines.

It is not always possible to predict to what extent QUERO XR 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 QUERO XR affects them.

QUERO XR contains lactose

QUERO XR contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take QUERO XR

Do not share medicines prescribed for you with any other person.
Always take/use QUERO XR exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Adults:

Bipolar depression, mania and schizophrenia:

Your doctor will decide on your starting dose. The maintenance (daily) dose will depend on your illness and needs, but will usually be between 50 mg and 800 mg per day.

Major Depressive Disorder (MDD):

Your doctor will decide on your starting dose. The maintenance (daily) dose will depend on your response, but will usually be 50 mg per day. An increase to 150 mg per day may occur and in extreme cases, your dose may be increased to 300 mg.

Special populations:

Elderly patients:

Your starting dose is usually 50 mg per day. The maintenance (daily) dose will depend on your illness and needs, but will usually be between 50 mg and 300 mg per day.

Patients with kidney problems:

No dose adjustments are necessary.

Patients with liver problems:

Your starting dose is usually 50 mg per day. Your doctor will decide on the maintenance (daily) dose.

Children and adolescents:

The safety and efficacy of QUERO XR have not been evaluated in children and adolescents.

Your doctor will tell you how long your treatment with QUERO XR will last. Do not stop treatment early because unwanted side-effects may occur.

If you have the impression that the effect of QUERO XR is too strong or too weak, tell your doctor or pharmacist.

If you take more QUERO XR than you should

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

Symptoms of overdose may include:

- sleepiness or drowsiness, feeling faint or dizzy and having palpitations (a rapid heartbeat), seizures, breathing difficulties, problems passing urine, confusion, delirium, agitation, coma and death.

If you forget to take QUERO XR

If you forget to take QUERO XR, take the missed dose as soon as you remember, then continue to take QUERO XR at the usual times. Do not take a double dose to make up for forgotten individual doses.

If you stop taking QUERO XR

If you suddenly stop taking QUERO XR, you may be unable to sleep (insomnia), feel sick (nausea), experience headache, diarrhoea, vomiting, dizziness or irritability. Your doctor will suggest you reduce the dose gradually, over a period of two weeks, before stopping treatment.

4. Possible side effects

QUERO XR can have side effects.

Not all side effects reported for QUERO XR are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while using QUERO XR, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop using QUERO XR 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 allergic reaction to QUERO XR. 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:

- changes in the way your heart beats, for example, if you notice it is beating faster
- difficulty breathing
- passing less urine than is normal for you
- Stevens-Johnson syndrome or other serious skin disorder (begins with flu-like symptoms, followed by a painful red or purplish rash that spreads and blisters), toxic epidermal necrolysis (can cause rash, blistering or peeling of the skin)
- sudden swelling and redness of the skin and the development of small white pus-filled spots (pustules) or inflammation involving capillaries or blood vessels in the skin causing skin discolouration
- thinking about or feeling like killing yourself

- fits or seizures
- yellowing of the skin and eyes caused by liver or blood problems (jaundice)
- hepatitis (inflammation of the liver with symptoms such as nausea, mild fever, abdominal pain), abnormal liver function (clay coloured stool, dark urine, itching, loss of appetite)
- a combination of high temperature (fever), sweating, stiff muscles, feeling very drowsy or faint, large increase in blood pressure heartbeat (a disorder called neuroleptic malignant syndrome)
- 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.

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:

- abnormal blood test results (decreases or increases in the number of certain types of blood cells)
- feeling faint or dizzy on standing up, low blood pressure
- increases in the amount of liver enzymes measured in the blood
- abnormal dreams, nightmares, mania (periods of great excitement or euphoria, delusions, and overactivity
- blocked or stuffy nose

- blurred vision
- disturbance in speech and language, feeling sleepy, tremors, slurred speech
- dry mouth, constipation, indigestion, vomiting
- bladder infection
- physical weakness, lack of energy, irritability, swelling of the arms or legs, fever
- discontinuation symptoms (symptoms which occur when you stop taking this medicine) include insomnia, nausea, headache, diarrhoea, vomiting, dizziness, and irritability
- increased appetite, increased blood sugar levels
- weight gain.

Less frequent side effects:

- diabetes or worsening of pre-existing diabetes, decrease in the amount of sodium in the blood
- inflammation of the pancreas (which causes severe pain in the abdomen and back), bowel obstruction
- breakdown of muscle fibers and pain in muscles
- unpleasant sensations in the legs (also called restless legs syndrome), involuntary movements of the face and jaw
- walking, talking, eating or other activities while you are asleep
- body temperature decreased (hypothermia)
- changes in the number of thyroid hormones in your blood

- increases in the amount of liver enzymes measured in the blood
- swelling of the breasts and unexpected production of breast milk, decreased sex drive, painful menstruation, prolonged painful erection, irregular menstruation
- metabolic syndrome (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 level).

The following side effects have been reported but the frequency for them to occur is not known:

- rapid or deep breathing with anxiety or panic, difficulty breathing
- stroke, high blood pressure
- symptoms of withdrawal may occur in new-born babies of mothers that have used QUERO XR during their pregnancy
- abdominal pain
- disorder of the heart muscle (cardiomyopathy)
- inflammation of the heart muscle (myocarditis).

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 QUERO XR. You can also send an email directly to the company, pharmacovigilance@pharmadynamics.co.za, to ensure safety of the product.

5. How to store QUERO XR

Store all medicines out of reach of children.

Store at or below 30 °C.

Keep in the outer carton until required for use.

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

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 QUERO XR contains

The active substance is quetiapine.

QUERO XR 50 mg: Each prolonged release tablet contains quetiapine fumarate equivalent to 50 mg quetiapine.

Contains sugar (14,21 mg lactose anhydrous per tablet).

QUERO XR 150 mg: Each prolonged release tablet contains quetiapine fumarate equivalent to 150 mg quetiapine.

Contains sugar (42,63 mg lactose anhydrous per tablet).

QUERO XR 200 mg: Each prolonged release tablet contains quetiapine fumarate equivalent to 200 mg quetiapine.

Contains sugar (56,84 mg lactose anhydrous per tablet).

QUERO XR 300 mg: Each prolonged release tablet contains quetiapine fumarate equivalent to 300 mg quetiapine.

CONTAINS SUGAR (85,26 mg lactose anhydrous per tablet).

QUERO XR 400 mg: Each prolonged release tablet contains quetiapine fumarate equivalent to 400 mg quetiapine.

Contains sugar (113,68 mg lactose anhydrous per tablet).

The other ingredients are:

Crystalline maltose, lactose anhydrous, magnesium stearate, methacrylic acid – ethyl acrylate copolymer, talc, triethyl citrate.

What QUERO XR looks like and contents of the pack

QUERO XR 50 mg: white to off white, film coated, round, biconvex tablet, engraved with ‘50’ on one side.

QUERO XR 150 mg: white to off white, film coated, oblong, biconvex tablet, engraved with ‘150’ on one side.

QUERO XR 200 mg: white to off white, film coated, oblong, biconvex tablet, engraved with ‘200’ on one side.

QUERO XR 300 mg: white to off white, film coated, oblong, biconvex tablet, engraved with ‘300’ on one side.

QUERO XR 400 mg: white to off white, film coated, oval, biconvex tablet, engraved with ‘400’ on one side.

White, opaque, PVC-PCTFE/aluminium blister strips, or white, opaque, HDPE bottles with child resistant polypropylene cap and induction seal liner containing either 10, 30 or 60 tablets.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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QUERO XR 300 mg: A49/2.6.5/0283

QUERO XR 400 mg: A49/2.6.5/0284