

QUTERO TABLETS

Quetiapine Fumarate Tablets (100mg,200mg,300mg)

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What QUTERO is used for

QUTERO can be used to treat several illnesses, such as:

- 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.
- Acute Mania episode: where you may feel very excited, elated, agitated, enthusiastic or hyperactive or have poor judgment including being aggressive or disruptive.
- Associated with bipolar disorder: (extreme mood swings ranging from episodes of depression to mania) where you may feel sad all the time or you may find that you feel depressed, feel guilty, lack energy, lose your appetite or can't sleep.

Your doctor may continue to prescribe Quetiapine Tablets even when you are feeling better.

How QUTERO works

QUTERO contains a substance called quetiapine. It belongs to a group of medicines called anti-psychotics. Illnesses that affects the brain, such as psychotic disorders may cause by lack of certain chemicals in the brain. QUTERO helps to put right this imbalance of chemicals in certain parts of the brain- mainly dopamine and serotonin.

Before you use QUTERO

When you must not use it

Do not take QUTERO if:

- you are allergic (hypersensitive) to quetiapine or any of the other ingredients of QUTERO
- QUTERO 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 this medicine.

- If you are taking any of the following medicines:
Some medicines for human immunodeficiency virus (HIV); azole medicines (for fungal infections); medicines for an infection (like erythromycin or clarithromycin); nefazodone (for depression).

Do not take QUTERO if the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking QUTERO.

Before you start to use it

Before you take your medicine, tell your doctor if you or someone in your family:

- Have or have had any heart problems, for example heart rhythm problems or if you are taking any medicines that may have impact on the way your heart beats.
- have low blood pressure
- Have had a stroke, especially if you are elderly.
- have problems with your liver
- have ever had a fit (seizure)
- have or are at a risk of having diabetes (e.g. being overweight or a family history of diabetes). Your doctor should check your blood sugar before you start taking QUTERO and regularly during treatment.
- 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 are an elderly person with dementia (loss of mental skills that affects your daily life). If you are, QUTERO should not be taken because the group of medicines that QUTERO belongs to may increase the risk of stroke, or in some cases the risk of death, in elderly people with dementia.

Pregnancy and breast feeding

Tell your doctor if you are pregnant, think that you may be pregnant or are planning to become pregnant. Do not take QUTERO until you and your

doctor have discussed the risks and benefits involved.

The following *extrapyramidal* and/or *withdrawal symptoms* may occur in newborn babies, of mothers that have used QUTERO in the last trimester (last three months of their pregnancy): Agitation, muscle stiffness and/or weakness, shaking, sleepiness, breathing problems, and difficulty in feeding. If your baby develops any of these symptoms you may need to contact your doctor.

Do not use this medicine if you are breast-feeding. This is because Quetero can be pass into the mother's milk.

Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding. Qutero should only be used in pregnancy if the benefits outweigh the risk to foetus.

Taking other medicines

Please tell your doctor if you are taking or have recently taken any other medicines because it may affect the way the medicine work. This includes medicines that you buy without a prescription and herbal medicines and combination of alcohol.

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

- Epilepsy medicines (like phenytoin or carbamazepine).
- Cytochrome P450 inhibitors (Ketoconazole, imipramine, fluoxetine)
- Barbiturates (for difficulty sleeping).
- Thioridazine, risperidone, or haloperidol (other antipsychotic medicine).
- Medicines that have an impact on the way your heart beats, for example, drugs that can cause an imbalance in electrolytes (low levels of potassium or magnesium) such as diuretics (water pills) or certain antibiotics (drugs to treat infections).

Taking QUTERO Tablets with food and drink

- QUTERO can be taken with or without food
- You should avoid alcohol while you

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are taking QUTERO. This is because the combined effect of QUTERO and alcohol can make you feel sleepy.

- Avoid grapefruit juice when on Qutero therapy.

How to use QUTERO

How much to use

Always take your medicine exactly as your doctor has told you. You should check with your doctor if you are not sure. Your doctor will decide on your starting dose and may gradually increase it depending on your illness and needs but will usually be between 150mg and 800mg.

Schizophrenia Adult

QUTERO should be administered 2 times daily, with or without food.

The usual starting dose is 25mg twice daily.

Antipsychotic efficacy dose range is of 150 to 750mg/day. The safety and efficacy doses above 800mg/day has not been evaluated.

Mania associated with Bipolar I Adult

QUTERO should be administered twice daily with or without food. Therapy is started with 100mg daily on the first day of treatment. The usual effective dose is 400 to 800mg per day.

Bipolar depression

QUTERO should be administered once daily at bedtime, with or without food. QUTERO is initiated at 50mg on the first day of therapy, and gradually increased to the target dose.

Maintenance Phase in Bipolar disorder as adjunct therapy to lithium or divalproex

Adults

Maintenance administered twice daily totaling 400mg to 800mg per day.

Liver problems

If you have liver problems your doctor may change your dose.

Elderly people

If you are elderly your doctor may change your dose. Rate of dose titration and daily therapeutic will be lower, depending on patients tolerability.

When to use it

Take QUTERO as instructed by your doctor or pharmacist.

- You will take your tablets twice or thrice a day, depending on your illness.
- Swallow your tablets whole with a drink of water.
- You can take your tablets with or without food.
- Do not drink grapefruit juice while you are taking QUTERO. It can affect the way the medicines work.
- Do not stop taking your tablets even if you feel better, unless your doctor tells you.

How long to use it

Do not stop taking QUTERO unless instructed by your doctor.

If you forget to use it

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 use too much (overdose)

If you take more QUTERO than prescribed by your doctor, you may feel sleepy, feel faint or dizzy and have palpitations (a pounding heart beat). Contact your doctor or nearest hospital straight away. Take the QUTERO with you.

While you are using it

Things you must do

Tell all the doctors, dentists and pharmacists treating you that you are taking Qutero.

Tell your doctor immediately if you become pregnant while taking this medication.

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 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).

Things you must not do

Do not stop taking the medicine even if you feel better unless your doctor told you so.

Things to be careful of

Driving and using machines

Your tablets may make you feel sleepy. Do not drive or use any tools or machines until you know how the tablets affect you.

Discontinuation Symptoms

If you suddenly stop taking QUTERO, you may be unable to sleep (insomnia), you may feel nauseous, or you may experience headache, diarrhoea, vomiting, dizziness or irritability. Gradual withdrawal over a period of at least 1 to 2 weeks is advisable.

Side Effects

Like all medicines, QUTERO can cause side effects, although not everybody gets them.

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any side effects not listed in this leaflet.

Very common: drowsiness, dizziness, dry mouth, mild weakness, constipation, rapid heartbeat (tachycardia), low blood pressure when standing causing dizziness, indigestion, headache, involuntary movement, withdrawal symptoms, high total cholesterol (high LDL), low HDL cholesterol, weight gain, low blood level.

Common: weight gain, fainting, neuroleptic malignant syndrome (characterized by a combination of high fever, sweating, stiff muscles, feeling very drowsy or faint, large increase in blood pressure or heartbeat), decreased white blood cell

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count, and swelling especially the lower limbs (peripheral oedema), high prolactin level, increased appetite, abnormal dreams and nightmares, abnormal or irregular heart rhythm, vision blurred, shortness of breath, constipation, indigestion/upset stomach, vomiting, mild weakness, swelling especially the 3 lower limbs (peripheral oedema), irritability, pyrexia, increase in liver enzymes (ALT, AST), Increase in blood sugar level and/or symptoms of high blood sugar (e.g. increased thirst, increased hunger, and frequent urination), trouble breathing during sleep (sleep apnoea),

Uncommon: increase of a type of white blood cells called eosinophils in blood, seizures, restless legs syndrome (Unpleasant leg sensations and an intense urge to move the legs), uncontrollable movements, mainly of the face or tongue (tardive dyskinesia), loss of consciousness, slower heartbeat, urinary retention (Difficulty or inability to pass urine), nasal congestion (rhinitis), difficulties in swallowing, elevation in an enzyme called AST, platelet count decreased, decreased in free triiodothyronine.

Rare: sleeping disorder and sleepwalking, intestinal obstruction, jaundice, a long-lasting and painful erection (priapism), milk secretion not due to breast-feeding, increase in blood creatine, lowered white blood cell count.

Very Rare: decrease in white blood cells called neutrophils, severe allergic reaction, diabetes mellitus, hepatitis, swelling of mucous membrane (angioedema), serious skin reaction known as Stevens-Johnson syndrome.

Not Known: Neonatal withdrawal

Quetiapine treatment was associated with small dose-related decreases in thyroid hormone levels, particularly total thyroxine and free thyroxine. The reduction in total and free thyroxine was maximal within the first two to four weeks of quetiapine treatment, with no further reduction during long-term treatment. In nearly all cases, cessation of Quetiapine treatment was associated with a reversal of the effects on total and free thyroxine, irrespective of the duration of treatment. Smaller

decreases in total triiodothyronine and reverse triiodothyronine were seen only at higher doses. Levels of Thyroxine-binding Globulin were unchanged and in general, reciprocal increases in Thyroid-Stimulating Hormone were not observed, with no indication that Quetiapine causes clinically relevant hypothyroidism

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of QUTERO

Storage

Store below 30 °C. Keep out of the reach and sight of children.

Disposal

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines that you no longer use.

These measures will help to protect the environment.

PRODUCT DESCRIPTION

What it looks like

QUTERO 100 (Quetiapine Fumarate Tablets 100mg): Yellow colored, round shaped, biconvex, film-coated tablets debossed with '55' on one side and 'I' on other side.

QUTERO 200 (Quetiapine Fumarate Tablets 200mg): White to off white colored, round shaped, biconvex, film-coated tablets debossed with '56' on one side and 'I' on other side.

QUTERO 300 (Quetiapine Fumarate Tablets 300mg): White to off white colored, capsule shaped, biconvex, film-coated tablets debossed with '45' on one side and 'I' on other side.

Ingredient(s)

The active substance is Quetiapine Fumarate.

Inactive Ingredients

Lactose Monohydrate, Calcium Hydrogen Phosphate Dihydrate, Cellulose Microcrystalline, Sodium Starch Glycolate, Povidone, Purified

Water, Magnesium Stearate, Opadry Yellow (For Quetiapine 100mg), & Opadry White (For Quetiapine 200mg & 300mg).

Registration number:

QUTERO 100 (Quetiapine Fumarate Tablets 100mg):

MAL18106036AZ

QUTERO 200 (Quetiapine Fumarate Tablets 200mg):

MAL18106037AZ

QUTERO 300 (Quetiapine Fumarate Tablets 300mg)

MAL18106038AZ

Manufacturer

Hetero Labs Limited, Unit – V, Sy. No. 439, 440, 441 & 458, TSIIC Formulation SEZ, Polepally Village, Jadcherla Mandal, Mahaboob Nagar (Dist.) – 509301, Telangana, India.

Product Registration Holder

Unimed Sdn Bhd
No.53, Jalan Tembaga SD 5/2B, Bandar Sri Damansara 52200, Kuala Lumpur, Malaysia.

Date of Revision

February 2024

Serial Number

NPRA(R2/1)250304/1425