

LEAFLET: INFORMATION FOR THE USER
Quetiapine Qualigen 300 mg film
coated tablets

Quetiapine

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Quetiapine Qualigen is and what it is used for
2. Before you take Quetiapine Qualigen
3. How to take Quetiapine Qualigen
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1. What Quetiapine Qualigen is and what it is used for

Quetiapine Qualigen belongs to a group of medicines called antipsychotics. It may have been prescribed for you to relieve the symptoms of schizophrenia.

Symptoms may include delirium (strange or unusual thoughts), delusion (seeing or sensing things which are not there), experience unusual behavior, which may be aggressive, leading even to social isolation or shyness, Quetiapine Qualigen is used to treat symptoms of schizophrenia or in moderate or severe mania episodes. These episodes may cause feeling enthusiastic or hyperactive. People under such circumstances may feel unusually suspicious, a necessity to sleep much less than usual and changes their minds too often. It has not been demonstrated that quetiapine avoid recurrence of maniac and depressive episodes.

2. Do not take it

- If you are hypersensitive (allergic) to quetiapine or any of the other Ingredients.
- If you are taking some medicines for HIV (against AIDS).
- If you are takingazole's medicines (for fungal infections) such as ketoconazole or itraconazol.
- If you are taking antibiotics, erythromycin or clarithromycin.
- If you are taking nefazodone for depression.

Warnings and precautions

- If you have low blood pressure.
- If you have any heart problem, heart rhythm problems or heart or blood vessel illness.
- 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 ever had a fit (seizure).
- If you have problems with your liver.
- If you have diabetes.
- If you have ever had a brain vessel accident.
- If you have had low levels of white blood cells.

Tell your doctor immediately if you experience after taking Quetiapine Qualigen that your heart beats quicker, fast breath, muscle stiffness, fever, uncontrollable movements of your face, body, arms and legs.

Interaction with other medicines

Tell your doctor or pharmacist if you are taking, have taken recently or should take another medicines even medicines based in medicinal plants, natural products or acquired without prescription.

Do not take it if you are taking

- Medicines for HIV (against AIDS).
- Azole's medicines (for fungal infections) such as ketoconazole or itraconazol.
- Antibiotics, erythromycin or clarithromycin.
- Nefazodone for depression.

Tell your doctor if you take RocoZ along with any of the following medicines

- Other medicines to treat mental diseases.
- Carbamazepin or phenytoin for epilepsy
- Medicines to treat abnormal heart rhythm.
- Medicines that could affect salt level in blood (potassium, magnesium).
- Some medicines may cause a quetiapine elimination from your body faster than usual and therefore your treatment may not work as well as it should.

Quetiapine Qualigen tablets with food, drinks and alcohol

Do not take grapefruit juice while you are taking quetiapine.

Do not drink any alcohol if you have been given Quetiapine Qualigen tablets

Quetiapine Qualigen can be taken with or without food.

Pregnancy, fertility and breast-feeding

Tell your doctor as soon as possible, if you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby. You do not take this medicine during pregnancy unless your doctor tells you so.

If your doctor prescribe you this medicine tell him if you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby.

The following symptoms may occur in new-born babies, of mothers that have used Quetiapine Qualigen tablets in the last trimester (last three months of their pregnancy): shaking, muscle stiffness and/or weakness, sleepiness, agitation, breathing problems, and difficulty in feeding. If your baby develops any of these symptoms you may need to contact your doctor.

Driving and using machines

Quetiapine Qualigen can produce symptoms such as drowsy, dizziness or sight disturbance and diminish reaction capacity. These symptoms along with illness can restrict your capacity to drive vehicles or operate machines. Therefore, do not drive, neither operate machines nor any other activity that requires special caution until your doctor evaluate your response to this medicine.

Important information upon some components of Quetiapine Qualigen

Quetiapine Qualigen tablets 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 Quetiapine Qualigen

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

Normal dosage is:

Adults

For schizophrenia treatment: normal initial dosage is 50mg. You should Take a number of tablets higher each of the first 4 days of treatment. From fourth day of treatment on, dosage can be increased depending on your response to treatment. Your doctor will tell you how many tablets you should take each day. Maximum daily dosage is 750mg each day.

For mania episode treatment linked to bipolar disorder: normal initial dosage is 100mg of quetiapine. From fourth day of treatment on, dosage can be increased depending on your response to treatment. Your doctor will tell you how many tablets you should take each day. Maximum daily dosage is 800mg each day.

Children and adolescents under 18.

Children and adolescents should not take quetiapine

Liver problems

If you have liver problems your doctor may prescribe a lower dose.

Elderly people

Your doctor may prescribe a lower dose.

Method of administration

Half of daily dosage should be taken in the morning and the other half in the evening.

Swallow your tablets whole with a drink of water. You can take your tablets with or without food.

If you take more Quetiapine Qualigen tablets than you should

In case of overdose or accidental ingestion, contact immediately your doctor or pharmacist, telling them the medicine and quantity taken.

Symptoms that may appear in case of overdose are: sleepiness and sedation, abnormal heart beats and low blood pressure (hypotension).

If you forget to take Quetiapine Qualigen

Do not take a double dose to make up for a forgotten tablet.

Take your tablets as soon as you remember unless you are close to next intake.

If you stop taking Quetiapine Qualigen tablets

Do not suddenly stop treatment without telling first your doctor as you may suffer symptoms such as nausea, vomiting and unable to sleep.

Quetiapine Qualigen treatment should be reduced gradually.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

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

Very common side effects (may affect more than 1 in 10 people):

Dizziness, feeling sleepy and headaches.

Common side effects (may affect up to 1 in 10 people):

Faint, rapid heartbeat, upset (indigestion), weakness, putting on weight, increased level of enzymes in blood, changes in levels of white blood cells, swelling of arms and legs, mouth dryness, constipation, rhinitis (itching, stuffy nose) or low blood pressure when standing up which may result in dizziness.

Uncommon side effects (may affect up to 1 in 100 people):

Seizure or attacks, cholesterol increase in blood and/or allergic reactions that cause red skin, itching, skin rash.

Rare side effects (may affect up to 1 in 1000 people):

Fever, a long-lasting and painful erection and/or jaundice (yellowing of the skin and eyes).

Very rare side effects (may affect up to 1 in 10.000 people):

A severe allergic reaction which may cause difficulty in breathing, dizziness and even shock. You should contact your doctor or emergency if you suffer any of these side effects.

Other very rare side effects are: increase of sugar level in blood, worsening of diabetes symptoms, hepatitis (liver inflammation), and abnormal muscle movements of the face, torso and arms and legs.

Not known frequency:

Blood clots in veins, especially in legs (symptoms included swelling, pain and leg rash), these clots can move through blood vessels reaching the lungs, causing breast pain and breath difficulty. If you get any side effects talk to your doctor immediately.

The class of medicines to which quetiapine belongs (antipsychotics) may cause heart rhythm problems, heart attacks or sudden death for unexplainable causes. Tell your doctor immediately if you feel breast pain, palpitation or irregular heartbeat.

It has been reported a little increase in number of deaths in elderly patients with insanity treated with antipsychotics in comparison with those that do not have this treatment.

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

5. How to store Quetiapine Qualigen

Keep this medicine out of the sight and reach of children.

This medicine does not require any special storage condition.

Do not use this medicine after the expiry date, which is stated on the carton.

The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Quetiapine Qualigen contents

The active substance is quetiapine fumarate.

Each coated tablet contains 300mg of quetiapine (as quetiapine fumarate) and 494.16mg of lactose monohydrate.

The other ingredients (excipients) are:

Tablet core: lactose monohydrate, microcrystalline cellulose, calcium hydrogen phosphate dihydrate, povidone K30, sodium starch glycolate (type A), calcium stearate.

Coating: hypromellose, titanium dioxide (E171), triacetin.

What Quetiapine Qualigen looks like and contents of the pack

Quetiapine Qualigen 300 mg are white film coated tablets, biconvex. Comes in blister and blisters in packs of 60 tablets.

Other presentations:

Quetiapine Qualigen 25 mg film coated tablets: packs of 6

or 60 tablets. Quetiapine Qualigen 100 mg film coated

tablets: packs of 60 tablets.

Quetiapine Qualigen 200 mg film coated tablets: packs of 60 tablets.

Manufacturer:

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Product License Holder

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