

KETIPINOR FILM-COATED TABLET

Quetiapine (25mg, 100mg, 200mg)

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What Ketipinor is used for

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

- *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)
- *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.

How Ketipinor works

Ketipinor contains a substance called quetiapine. It belongs to a group of medicines called antipsychotics. Illnesses that affect the brain, such as psychotic disorders may be caused by lack of certain chemicals in the brain. Ketipinor helps to put right this imbalance of chemicals in certain parts of the brain – mainly dopamine and serotonin.

Before you use Ketipinor

- When you must not use it

Do not take Ketipinor

- if you are allergic (hypersensitive) to quetiapine or any of the other ingredients of Ketipinor (see section **Product Description**)
- if you are taking any of the following medicines:
 - some medicines for human immunodeficiency virus (HIV)

- azole medicines (for fungal infections)
- erythromycin or clarithromycin (for infections)
- nefazodone (for depression).

- Before you start to use it

Talk to your doctor before taking Ketipinor 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 an impact on the way your heart beats.
- you have low blood pressure.
- you have had a stroke, especially if you are elderly.
- you have problems with your liver.
- you have ever had a fit (seizure).
- 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 Ketipinor.
- 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, Ketipinor should not be taken because the group of medicines that Ketipinor 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 Ketipinor 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 Ketipinor 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 small amounts may pass into the mother's milk.

Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding.

- 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.

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

- epilepsy medicines (like phenytoin or carbamazepine).
- barbiturates (for difficulty sleeping).
- thioridazine (another anti-psychotic 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).

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

How to use Ketipinor

- How much to use

Always take this medicine exactly as your doctor has told you. Check with

your doctor or pharmacist if you are not sure.

Your doctor will decide on your starting dose. The maintenance dose (daily dose) will depend on your illness and needs but will usually be between 150 mg and 800 mg.

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.

Use in children and adolescents

There are no data on the use of Ketipinor in children and adolescents.

- When to use it

Use as directed 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 Ketipinor. It can affect the way the medicines works.
- Do not stop taking your tablets even if you feel better, unless your doctor tells you.

- How long to use it

Continue taking Ketipinor for as long as your doctor recommends.

- 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 for the next dose, wait until then. Do not take a double dose to make up for a forgotten tablet.

- If you use too much (overdose)

If you take more Ketipinor than prescribed by your doctor, you may feel sleepy, feel dizzy and experience abnormal heart beats. Contact your doctor or nearest hospital straight away. Take the Ketipinor tablets with you.

While you are using it

- Things you must do

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

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 take any new medicines without consulting your doctor.

Do not give Ketipinor to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

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

Discontinuation symptoms

Symptoms which occur when you stop taking Ketipinor include not being able to sleep (insomnia), feeling sick (nausea),

headache, diarrhoea, being sick (vomiting), dizziness and irritability. Gradual withdrawal over a period of at least 1 to 2 weeks is advisable.

Ketipinor contains lactose. The lactose content in 100 mg tablets is 20.7 mg and in 200 mg tablets 41.4 mg. If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicinal product.

Side effects

Like all medicines, this medicine 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 (affects more than 1 in 10 people):

- dizziness (may lead to falls), headache, dry mouth.
- feeling sleepy (this may go away with time, as you keep taking Ketipinor) (may lead to falls).

Common (affects less than 1 in 10 people):

- rapid heartbeat
- stuffy nose
- constipation, upset stomach (indigestion)
- feeling weak, fainting (may lead to falls)
- swelling of arms or legs
- low blood pressure when standing up. This may make you feel dizzy or faint (may lead to falls)
- putting on weight.

Uncommon (affects less than 1 in 100 people):

- fits or seizures
- allergic reactions that may include raised lumps (weals), swelling of the skin and swelling around the mouth
- change in electrical activity of the heart seen on ECG (QT prolongation).

Rare (affects less than 1 in

1,000 people):

- a combination of high temperature (fever), sweating, stiff muscles, feeling very drowsy or faint (a disorder called “neuroleptic malignant syndrome”)
- yellowing of the skin and eyes (jaundice)
- a long-lasting and painful erection (priapism)

Very rare (affects less than 1 in 10,000 people):

- severe rash, blisters or red patches on the skin
- a severe allergic reaction (called anaphylaxis) which may cause difficulty in breathing or shock
- rapid swelling of the skin, usually around the eyes, lips and throat (angioedema)
- increased levels of sugar in the blood
- abnormal muscle movements. These include difficulty starting muscle movements, shaking, feeling restless or muscle stiffness without pain.
- shortness of breath

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers →Reporting).

Storage and Disposal of Ketipinor**- Storage**

Store your medicine 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**

Ketipinor 25 mg is brown/dark pink, round, convex, film coated tablet, diameter 6 mm.

Ketipinor 100 mg is light yellow, round, convex, film-coated tablet, diameter 8 mm.

Ketipinor 200 mg is white, round, convex, film-coated tablet, diameter 11 mm.

- Ingredients

- Active ingredient
Quetiapine (as fumarate).

- Inactive ingredients

25 mg tablet: microcrystalline cellulose, croscarmellose sodium, povidone (K30) and magnesium stearate, Opadry II (Opadry II contains partly hydrolysed polyvinyl alcohol, macrogol, talc, titanium dioxide (E 171) and iron oxides (E 172)).

100 mg tablet: microcrystalline cellulose, calcium hydrogen phosphate dihydrate, lactose monohydrate, sodium starch glycolate (Type A), povidone (K30) and magnesium stearate, Opadry II (Opadry II contains partly hydrolysed polyvinyl alcohol, macrogol, talc, titanium dioxide (E 171) and iron oxides (E 172)).

200 mg tablet: microcrystalline cellulose, calcium hydrogen phosphate dihydrate, lactose monohydrate, sodium starch glycolate (Type A), povidone (K30) and magnesium stearate, Opadry II (Opadry II contains partly hydrolysed polyvinyl alcohol, macrogol, talc and titanium dioxide (E 171)).

- MAL number(s):

Ketipinor 25mg: MAL09072787AZ

Ketipinor 100mg: MAL09072789AZ

Ketipinor 200mg: MAL09072788AZ

Manufacturer

Orion Corporation, Orion Pharma
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Product Registration Holder

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