

QUETIAPINE ACTAVIS TABLETS

Quetiapine Fumarate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some of the common questions people ask about QUETIAPINE ACTAVIS. It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor will have weighed the risks of you taking it against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What QUETIAPINE ACTAVIS is used for

QUETIAPINE ACTAVIS helps to correct chemical imbalances in the brain. It is used to treat conditions such as:

- Schizophrenia, an illness with disturbances in thinking, feelings and behaviour
- Bipolar disorder, an illness in which there are sustained mood swings either up (mania) or down (depression). During mania, patients experience episodes of overactivity, elation or irritability. During depression, patients may feel depressed or guilty, lack energy, lose their appetite and have trouble sleeping.

QUETIAPINE ACTAVIS belongs to a group of medicines called antipsychotics.

Ask your doctor if you have any questions about why it has been prescribed for you.

Your doctor may prescribe this medicine for another reason.

It is not addictive.

This medicine is available only with a doctor's prescription.

Before you take it

When you must not take it

Do not take QUETIAPINE ACTAVIS if you have an allergy to

- quetiapine, the active ingredient in the medicine
- any of the other ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin or you may feel faint.

Do not give QUETIAPINE ACTAVIS to children or adolescents unless recommended by your doctor.

The effects of QUETIAPINE ACTAVIS have only been studied in children aged between 10 and 17 years with mania and in children aged between 13 and 17 years with schizophrenia. There is not enough information on its effects in children to recommend its use in other age groups or for other conditions.

Do not use it after the use by (expiry) date printed on the pack.

Do not use it if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking QUETIAPINE ACTAVIS, talk to your doctor or pharmacist.

Before you start to take it

Tell your doctor if you have any allergies to:

- any other medicines
- any other substances, such as foods, dyes or preservatives

Tell your doctor if you have or have had any medical conditions, especially the following:

- heart or blood vessel problems or a family history of heart or blood vessel problems including low blood pressure, stroke, problems with your circulation or any condition that affects blood flow to the brain, problems with the way your heart beats or a history of heart attack
- liver problems
- diabetes (or a family history of diabetes). Patients with diabetes or who have a higher chance of diabetes should have their blood sugar checked before and during treatment with QUETIAPINE ACTAVIS.
- epilepsy (seizures or fits)
- dementia or related behavioural disorders (especially in elderly patients)
- low white blood cell count

Tell your doctor or mental health professional if you have any mental/mood changes or suicidal thoughts.

Depression and other mental illnesses can increase the risk of suicide. It is important to discuss all the risks of treating depression and mental illness as well as the risks of not treating it.

You should discuss all treatment choices with your doctor, not just the use of antidepressants.

Patients (and caregivers of patients) need to monitor for any worsening of their condition and/or the emergence of thoughts of suicide or suicidal behaviour or thoughts of harming themselves and to seek medical advice immediately if these symptoms present.

Do not take QUETIAPINE ACTAVIS if you are pregnant or breastfeeding unless your doctor says so. Ask your doctor about the risks and benefits involved.

QUETIAPINE ACTAVIS may affect your baby after delivery if you take it during the third trimester of pregnancy.

However, if you need to take it during your pregnancy, the doctor will discuss the risks and benefits of taking it with you.

It is recommended that you do not breastfeed while taking it, as it is not known whether it passes into breast milk.

Before your doctor starts you on QUETIAPINE ACTAVIS your doctor may want to take some tests (eg blood tests, blood pressure, weight or height measurements). These tests may help to prevent side effects.

Tell your doctor if you are lactose intolerant.

QUETIAPINE ACTAVIS tablets contain lactose.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from

your pharmacy, supermarket or health food shop.

Some medicines and QUETIAPINE ACTAVIS may interfere with each other. These include:

- medicines used to treat anxiety, depression, mood swings, attention deficit hyperactivity disorder (ADHD) or other mood disorders
- lorazepam - a medicine used to help you sleep
- phenytoin or carbamazepine - medicines for epilepsy
- medicines for high blood pressure (including diuretics or fluid tablets) for heart conditions
- some antibiotics such as rifampicin and erythromycin
- medicines used for fungal infections such as ketoconazole
- medicines for Human Immunodeficiency Virus (HIV)
- thioridazine - an antipsychotic medicine
- medicines used to treat Parkinson's disease
- stimulants such as amphetamines
- glucocorticoids - medicines used to treat inflammation

These medicines may be affected by QUETIAPINE ACTAVIS, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking QUETIAPINE ACTAVIS.

If you have not told your doctor about any of these things, tell them before you take any QUETIAPINE ACTAVIS.

How to take it

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the pack, ask your doctor or pharmacist for help.

How much to take

Your doctor will tell you how many tablets you will need to take each day and how long you need to take it.

This depends on your condition and whether or not you are taking any other medicines.

QUETIAPINE ACTAVIS is usually started as a low dose that will be gradually increased by your doctor. Your doctor will recommend a dose especially for you. This will depend on various factors including your age, condition being treated, other medical conditions (eg liver problems), other medicines you are taking and how you may react to QUETIAPINE ACTAVIS. Your doctor will monitor your condition and may change your dose depending on how you respond to it. Your doctor will use the lowest dose for the least amount of time to keep you well.

When to take it

QUETIAPINE ACTAVIS is taken once or twice a day depending on your condition. Your doctor will tell you how you should take it.

Swallow your QUETIAPINE ACTAVIS tablets whole with a full glass of water.

You can take them with or without food.

How long to take it

Continue taking the tablets for as long as your doctor tells you.

QUETIAPINE ACTAVIS helps control your condition, but does not cure it.

Therefore you must take it every day.

Do not stop taking it unless your doctor tells you to - even if you feel better.

If you forget to take it

If it is almost time for your next dose (within 6 hours), skip the dose you missed and take your next dose when you are meant to. Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose you have missed.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (13 11 26) for advice or go to Accident and Emergency at your nearest hospital if you think that you or anyone else may have taken too much QUETIAPINE ACTAVIS. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too many QUETIAPINE ACTAVIS tablets you may feel drowsy, sleepy, dizzy or have fast heart beats.

While you are taking it

Things you must do

Tell any other doctors, dentists, and pharmacists who are treating you that you are taking it.

If you are about to be started on any new medicines, tell your doctor, dentist or pharmacist that you are taking it.

Tell your doctor or mental health professional immediately, or go to the nearest hospital, if you have any of the following suicidal thoughts or other mental/mood changes:

- thoughts or talk of death or suicide
- thoughts or talk of self-harm or harm to others
- any recent attempts of self-harm
- increase in aggressive behaviour, irritability or agitation
- worsening of depression

Occasionally, the symptoms of depression may include thoughts of suicide or self-harm. These symptoms may continue or get worse during the early stages of treatment until the effect of the medicine becomes apparent. All mentions of suicide or violence must be taken seriously.

If you become pregnant while taking it, tell your doctor immediately.

If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking it.

If you need to have any medical tests (including urine drug screening) while you are taking it, tell your doctor.

It may affect the results of some tests.

Be sure to keep all of your doctor's appointments so that your progress can be checked.

Your doctor will check your progress and may want to take some tests (eg blood tests, blood pressure, weight or height measurements) from time to time. These tests may help to prevent side effects.

Things you must not do

Do not stop taking it, or change the dosage, even if you are feeling better, without checking with your doctor.

If you stop taking it suddenly, your condition may worsen or your chance of getting an unwanted side effect may increase. To prevent this,

your doctor may gradually reduce the amount of QUETIAPINE ACTAVIS you take each day before stopping completely.

Do not give it to anyone else, even if their symptoms seem similar or they have the same condition as you.

Do not take it to treat any other complaints unless your doctor tells you to.

Do not take any medicines that cause drowsiness while you are taking it, unless recommended by your doctor.

Things to be careful of

Be careful driving or operating machinery until you know how QUETIAPINE ACTAVIS affects you.

It can make some people dizzy or sleepy. Make sure you know how you react to it before you do anything that could be dangerous if you are dizzy or sleepy. Children should be careful when riding bicycles or climbing trees.

If it makes you feel light-headed, dizzy or faint, be careful when getting up from a sitting or lying position.

Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

Be careful when drinking alcohol while you are taking it.

Combining QUETIAPINE ACTAVIS and alcohol can make you more sleepy or dizzy. Your doctor may suggest you avoid alcohol while you are being treated with it.

Avoid getting over-heated or dehydrated - do not over-exercise, in hot weather stay inside in a cool place, stay out of the sun, do not wear too much or heavy clothing, drink plenty of water. Keep warm in cool weather. QUETIAPINE ACTAVIS may affect the way your body reacts to temperature changes.

Avoid drinking large quantities of grapefruit juice.

This medicine may be affected by grapefruit juice. Talk to your doctor or pharmacist if you have any concerns.

Talk to your doctor or pharmacist about these things if you think they may bother you.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking it.

All medicines can have side effects.

Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects. Some side effects may be related to the dose of QUETIAPINE ACTAVIS or may be more likely to occur during long term treatment.

Therefore, it is important that you tell your doctor as soon as possible if you notice anything that is making you feel unwell, even if you think the problems are not connected with this medicine. Your doctor may then decide to adjust your dose or use a different medicine.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- feeling sleepy
- weight gain, increased appetite
- feeling weak
- dry mouth
- runny or stuffy nose
- indigestion, upset stomach, constipation, vomiting (mainly in elderly)
- swelling of your hands, feet or ankles
- blurred vision
- abnormal dreams, nightmares
- irritability

- Shortness of breath, difficulty in breathing and/or tightness in the chest
- Fast or irregular heartbeats (palpitations)

These side effects are usually mild.

Some of these side effects may go away after a while.

Tell your doctor as soon as possible if you notice the following:

- falling, feeling dizzy or faint on standing up
- difficulty in speaking
- difficulty swallowing
- rapid heart beat
- symptoms of high sugar levels in the blood (including passing large amounts of urine, excessive thirst, increase in appetite with a loss of weight, feeling tired, drowsy, weak, depressed, irritable and generally unwell)
- breast enlargement, unusual secretion of breast milk

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

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- long lasting and painful erection
- fainting
- signs of frequent infections such as fever, chills, sore throat or mouth ulcers
- bleeding or bruising more easily than normal
- very marked drowsiness
- reduced consciousness
- abnormal muscle movements, including difficulty starting muscle movements, shaking, restlessness or muscle stiffness without pain.
- worm-like movements of the tongue or other uncontrolled movements of the tongue, mouth, cheeks or jaw which may progress to the arms and legs

- a sudden increase in body temperature, with sweating, or a fast heart beat
- fits (seizures)
- severe allergic reaction (may include severe difficulty breathing, shock, swelling of the face, lips, tongue or other parts of the body, skin rash, hayfever, or you may feel faint)

These are very serious side effects.

You may need urgent medical attention or hospitalisation.

Occasionally, QUETIAPINE ACTAVIS may be associated with changes in your liver function or blood (eg blood fat levels such as cholesterol or triglycerides, blood sugar levels, blood pressure, thyroid hormone levels).

These can only be found when your doctor does tests from time to time to check your progress.

Other side effects not listed above may occur in some patients. Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After taking it

Storage

Keep your QUETIAPINE ACTAVIS tablets in the blister pack until it is time to take them.

If you take the tablets out of the blister pack they will not keep well.

Keep it in a cool dry place where the temperature stays below 25°C.

Do not store it or any other medicine in the bathroom or near a sink. Do not leave it in the car or on a window sill.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking it or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What QUETIAPINE ACTAVIS looks like

QUETIAPINE ACTAVIS tablets are film-coated. All tablets except 300 mg are embossed with "Q" and the strength on one side, and are plain on the other side.

QUETIAPINE ACTAVIS 300 mg tablets are embossed with "Q" on one side and "300" on the other.

Tablet shape and colouring is as follows:

- 25 mg: round light orange
- 100 mg: round yellow
- 200 mg: oval white
- 300 mg: oval white.

The available pack sizes are:

- 25 mg: 10, 30, 60, 90, 100 tablets
- 100 mg: 10, 30, 60, 90, 100 tablets
- 200 mg: 10, 30, 50, 60 tablets
- 300 mg: 10, 30, 50, 60 tablets

Ingredients

Each tablet contains quetiapine fumarate as the active ingredient equivalent to quetiapine 25 mg, 100 mg, 200 mg or 300 mg.

Other ingredients include:

- Povidone
- Calcium hydrogen phosphate
- Cellulose microcrystalline
- Sodium starch glycollate Type A

- Lactose
- Magnesium stearate
- Opadry II Pink 33G34594 (25mg tablets only)
- Opadry II Yellow 33G32578 (100mg tablets only)
- Opadry II White 33G28435 (200mg and 300mg tablets only)

QUETIAPINE ACTAVIS tablets do not contain gluten or sucrose.

Sponsor

Amneal Pharma Australia Pty Ltd
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South Yarra VIC 3141
Australia

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QUETIAPINE ACTAVIS 25 mg:
179898

QUETIAPINE ACTAVIS 100 mg:
179904

QUETIAPINE ACTAVIS 200 mg:
179900

QUETIAPINE ACTAVIS 300 mg:
179899