

# Quetiaccord Tablets

*Quetiapine fumarate*

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## Consumer Medicine Information

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### What is in this leaflet

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This leaflet answers some of the common questions people ask about Quetiaccord Tablets. 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 Quetiaccord Tablets 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.

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### What Quetiaccord Tablets are used for

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Quetiaccord Tablets 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.

Quetiaccord Tablets 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.

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### Before you take it

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*When you must not take it*

**Do not take Quetiaccord Tablets if you have an allergy to:**

- **quetiapine, the active ingredient in Quetiaccord Tablets**
- **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 Quetiaccord Tablets to children or adolescents unless recommended by your doctor.**

The effects of Quetiaccord Tablets 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 Quetiaccord Tablets after the use by (expiry) date printed on the pack.**

**Do not use Quetiaccord Tablets 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 Quetiaccord Tablets, 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 Quetiaccord Tablets.
- 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 Quetiaccord Tablets if you are pregnant or breastfeeding unless your doctor says so. Ask your doctor about the risks and benefits involved.**

It is not known if it is safe for you to take it while you are pregnant. 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 may pass into breast milk.

Before your doctor starts you on Quetiaccord Tablets 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.**

Quetiaccord 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 Quetiaccord Tablets 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) or 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 medicines
- medicines used to treat Parkinson's disease
- stimulants such as amphetamines
- glucocorticoids - medicines used to treat inflammation.

These medicines may be affected by Quetiaccord Tablets, 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 Quetiaccord Tablets.

**If you have not told your doctor about any of these things, tell them before you take any Quetiaccord Tablets.**

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## How to take it

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**Follow all directions given to you by your doctor and 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.

Quetiaccord Tablets are 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 Quetiaccord Tablets. 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*

Quetiaccord Tablets are taken once or twice a day depending on your condition. Your doctor will tell you how you should take Quetiaccord Tablets.

**Swallow your Quetiaccord 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.**

Quetiaccord Tablets helps control your condition, but does not cure it. Therefore you must take Quetiaccord Tablets everyday.

Do not stop taking Quetiaccord Tablets 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 Quetiaccord Tablets 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 Poisons Information Centre (13 11 26) for advice or go to Accident and Emergency at your nearest hospital, if you think you or anyone else may have taken too much Quetiaccord Tablets. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too many Quetiaccord Tablets you may feel drowsy, sleepy, dizzy or have fast heart beats.

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## While you are taking it

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### *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 Quetiaccord Tablets, 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 Quetiaccord Tablets 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 Quetiaccord Tablets affect 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 Quetiaccord Tablets 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.**

Quetiaccord Tablets 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.**

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## Side Effects

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### **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 Quetiaccord Tablets 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 (particularly in children)
- indigestion, upset stomach, constipation, vomiting (mainly in elderly or children)
- 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 (particularly in children)
- 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)
- severe upper stomach pain, often with nausea and vomiting (particularly in patients with other risk factors such as gallstones, alcohol consumption and/or increased levels of certain fats within the blood)

These are very serious side effects.

You may need urgent medical attention or hospitalisation.

Occasionally, Quetiaccord Tablets 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, white blood cells). 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.

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## After taking it

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### *Storage*

### **Keep your Quetiaccord Tablets in the blister pack until it is time to take them.**

If you take Quetiaccord 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 Quetiaccord Tablets or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.**

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## Product Description

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### *What Quetiaccord Tablets looks like*

The following Quetiaccord tablets are:

Round, biconvex, film-coated tablets plain on both sides.

- 25 mg - pink coloured
- 100 mg - yellow coloured
- 200 mg - white to off-white coloured.

The following Quetiaccord tablet is capsule shaped, biconvex, film-coated tablet, with '300' debossed on one side and plain on other side:

- 300 mg - white to off-white coloured.

The pack sizes for each strength are:

- Quetiaccord Tablets 25 mg - 20 or 60 tablets.
- Quetiaccord Tablets 100 mg - 20 or 90 tablets.
- Quetiaccord Tablets 200 mg - 20 or 60 tablets.
- Quetiaccord Tablets 300 mg - 20, 60 or 100 tablets.

Quetiaccord tablets are packed in PVC/aluminium blister pack.

### *Ingredients*

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

plus,

- Lactose,
- Sodium starch glycollate (Type A),
- Calcium hydrogen phosphate,
- Povidone,
- Microcrystalline cellulose (E 460),
- Magnesium stearate (E572).

Film-coating contains

- opadry complete film coating system 03B84929 pink (ARTG No.106711) [25 mg],
- opadry complete film coating system 03B52117 yellow (ARTG No.106712) [100 mg],
- hypromellose, macrogol 400 and titanium Dioxide [200 mg, 300 mg].

Quetiaccord tablets do not contain gluten or sucrose.

### *Name and Address of the Sponsor*

#### **Accord Healthcare Pty Ltd.**

Unit 702/23,  
Queens Road,  
Melbourne, Victoria, 3004  
Australia

**Quetiaccord Tablets 25 mg:** AUST R 170852

**Quetiaccord Tablets 100 mg:** AUST R 170855

**Quetiaccord Tablets 200 mg:** AUST R 170850

**Quetiaccord Tablets 300 mg:** AUST R 170857

#### **Date of first inclusion in the ARTG:**

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