

## APO-QUETIAPINE XR

Contains the active ingredient quetiapine (as fumarate)

### Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

#### What is in this leaflet

##### Read this leaflet carefully before taking your medicine.

This leaflet answers some common questions about APO-QUETIAPINE XR. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

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

Keep this leaflet with your medicine. You may want to read it again.

#### What this medicine is used for

The name of your medicine is APO-QUETIAPINE XR Tablet. It contains the active ingredient quetiapine fumarate.

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

- 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.
- Recurrent major depressive disorder, an illness where depression is longer lasting and/or more severe than the "low moods" everyone has from time to time due to the stress of everyday life. It is thought to be caused by a chemical imbalance in parts of the brain. This imbalance affects your whole body and can cause emotional and physical symptoms such as feeling low in spirit, loss of interest in activities, being unable to enjoy life, poor appetite or overeating, disturbed sleep, often waking up early, loss of sex drive, lack of energy and feeling guilty over nothing.
- Generalised anxiety disorder, where patients have excessive anxiety and worry.
- Schizophrenia, an illness with disturbances in thinking, feelings and behaviour.

Ask your doctor if you have any questions about why this medicine has been prescribed for you. Your doctor may have prescribed this medicine for another reason.

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

##### How it works

This medicine belongs to a group of medicines called antipsychotics

There is no evidence that this medicine is addictive.

#### Before you take this medicine

##### When you must not take it

This medicine is not recommended for use in children.

There is not enough information on its effects in children.

##### Do not take this medicine if:

- You are hypersensitive to, or have had an allergic reaction to, quetiapine or any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include: cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin; fainting; and/or hay fever-like symptoms.

**If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.**

- The expiry date (EXP) printed on the pack has passed.
- The packaging is torn, shows signs of tampering or it does not look quite right.

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

##### Before you start to take it

**Before you start taking this medicine, tell your doctor if:**

1. You have allergies to:
  - any other medicines
  - any other substances, such as foods, preservatives or dyes.
2. 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 this medicine.
  - epilepsy (seizures or fits)
  - dementia or related behavioural disorders (especially in elderly patients)
  - low white blood cell count
  - sleep apnoea - a condition where you stop breathing for short periods during your normal nightly sleep.
  - urinary retention (a condition where you can't completely empty your bladder)
  - an enlarged prostate
  - a blockage in your intestines
  - increased pressure inside your eyes or glaucoma

**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.

3. You are currently pregnant or you plan to become pregnant. Do not take this medicine whilst pregnant until you and your doctor have discussed the risks and benefits involved. It is not known if it is safe for you to take it while you are pregnant
4. You are currently breastfeeding or you plan to breast-feed. Do not take this medicine whilst breastfeeding until you and your doctor have discussed the risks and benefits involved. It is recommended that you do not breast-feed while taking it, as it may pass into breast milk.
5. You are planning to have surgery or an anaesthetic.
6. You are currently receiving or are planning to receive dental treatment.
7. You are taking or are planning to take any other medicines. This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

Before your doctor starts you on this medicine 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.** This medicine contains lactose.

##### Taking other medicines

Some medicines may interact with APO-QUETIAPINE XR. These include:

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

These medicines may be affected by APO-QUETIAPINE XR, or may affect how well it works. If you are taking any of these you may need a different dose or you may need to take different medicines.

Your doctor and pharmacist have more information about medicines to be careful with or avoid while taking this medicine.

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

Other medicines not listed above may also interact with quetiapine.

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## How to take this medicine

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Follow carefully all directions given to you by your doctor. Their instructions may be different to the information 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 will depend on your condition and whether you are taking any other medicines.

Do not stop taking your medicine or change your dosage without first checking with your doctor.

This medicine is usually started as a low dose that will be 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 this medicine.

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.

Your doctor may have switched your treatment from quetiapine immediate release tablets to this medicine. Your doctor will generally prescribe you a once daily dose of this medicine, which is equivalent to your total daily dose of quetiapine immediate release tablets.

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

### How to take it

Swallow this medicine whole with a full glass of water. Do not split, chew or crush the tablets.

If you split, chew or crush the tablets they will not work properly.

### When to take it

Take this medicine once a day at the same time each day. Taking it at the same time each day will have the best effect and will also help you remember when to take it.

It should be taken without food.

### How long to take it for

Continue taking your medicine for as long as your doctor tells you.

This medicine 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.

Make sure you have enough to last over weekends and holidays.

### If you forget to take it

If it is almost time to take your next dose, skip the missed dose and take your next dose at the usual time. 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 missed doses.

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

This may increase the chance of you experiencing side effects.

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

### If you take too much (overdose)

**If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively, go to the Accident and Emergency department at your nearest hospital.**

**Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.**

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

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## While you are taking this medicine

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### Things you must do

Tell any other doctors, dentists, and pharmacists who are treating you that you are taking this medicine if:

- you are about to be started on any new medicine
- you are pregnant or are planning to become pregnant
- you are breastfeeding or are planning to breast-feed
- you are about to have any blood tests or medical tests (including urine drug screening)
- you are going to have surgery that needs a general anaesthetic or an anaesthetic or are going into hospital.

**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.

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.

Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

### Things you must not do

#### Do not:

- Give this medicine to anyone else, even if their symptoms seem similar or they have the same condition as you.
- Take your medicine to treat any other condition unless your doctor tells you to.
- Stop taking your medicine, or change the dosage, even if you are feeling better, without first 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 this medicine you take each day before stopping completely.

- Take any medicines that cause drowsiness while you are taking it, unless recommended by your doctor.

### Things to be careful of

**Be careful when driving or operating machinery until you know how this medicine affects you.**

It can make some people dizzy or sleepy. Make sure you know how you react to it before you drive a car, operate machinery or do anything else that could be dangerous if you are dizzy or sleepy.

**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 this medicine 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.**

This medicine 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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## Possible side effects

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Tell your doctor as soon as possible if you do not feel well while you are taking APO-QUETIAPINE XR or if you have any questions or concerns.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but 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 this medicine 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:**

- feeling sleepy
- weight gain, increased appetite
- dry mouth
- upset stomach, constipation, indigestion, vomiting (mainly in elderly or children)
- feeling weak
- swelling of the hands, ankles or feet
- runny or stuffy nose (particularly in children)
- 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 any of the following.**

These may be serious side effects and you may need medical attention:

- difficulty swallowing
- falling, feeling dizzy or faint on standing up
- difficulty in speaking
- 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

**If you experience any of the following, stop taking your medicine and contact your doctor immediately or go to the Accident and Emergency department at your nearest hospital.**

These are very serious side effects and you may need urgent medical attention or hospitalisation:

- 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
- bleeding or bruising more easily than normal
- very marked drowsiness
- reduced consciousness
- fits (seizures)
- long-lasting and painful erections
- fainting (particularly in children)
- severe allergic reaction (may include severe difficulty in breathing, shock, swelling of the face, lips, tongue or other parts of the body, skin rash, hay fever, or you may feel faint)
- signs of frequent infections such as fever, chills, sore throat or mouth ulcers
- 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).

Occasionally, this medicine may be associated with changes in your liver function or blood (eg blood fat levels such as cholesterol or triglyceride, 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.

#### **Allergic reactions**

**If you think you are having an allergic reaction to Quetiapine XR, do not take any more of this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.**

Symptoms of an allergic reaction may include some or all of the following:

- cough, shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue, throat or other parts of the body
- rash, itching or hives on the skin
- fainting
- hay fever-like symptoms.

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#### **Storage and disposal**

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##### **Storage**

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 25°C.

Do not store your medicine, or any other medicine, in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

**Keep this medicine where 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 this medicine or it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

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#### **Product description**

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##### **What APO-QUETIAPINE XR Tablet looks like**

Apo-Quetiapine XR 50 mg tablets: Peach coloured, round shaped, biconvex film coated tablets, debossed with 'Q50' on one side and plain on other.

Apo-Quetiapine XR 200 mg tablets: Yellow coloured, round shaped, biconvex film coated tablets, debossed with 'I2' on one side and plain on other.

Apo-Quetiapine XR 300 mg tablets: Light yellow coloured, round shaped, biconvex film coated tablets, debossed with 'Q300' on one side and plain on other.

Apo-Quetiapine XR 400 mg tablets: White coloured, round shaped, biconvex, film coated tablets, debossed with 'I4' on one side and plain on other.

All strengths are available in packs\* of 10, 30, 60 or 100 tablets.

\* Not all strengths, pack types and/or pack sizes may be available.

##### **Ingredients**

Each APO-QUETIAPINE XR tablet contains quetiapine fumarate as the active ingredient equivalent to quetiapine 50 mg, 200 mg, 300 mg or 400 mg.

It also contains the following inactive ingredients:

- lactose
- hypromellose
- sodium chloride
- povidone
- talc
- magnesium stearate

The 50 mg tablet also contains Opadry II 85F540003 Pink - PI no. 109248 and microcrystalline cellulose.

The 200 mg tablet also contains Opadry 03B52117 Yellow - PI no. 106712.

The 300 mg tablet also contains Opadry 03B82929 yellow - PI no. 106295

The 400 mg tablet also contains Opadry 03B58900 white - PI no.106176.

This medicine is gluten-free, sucrose-free, tartrazine-free and free of other azo dyes.

#### **Australian Registration Numbers**

APO-QUETIAPINE XR Tablet (Blister Pack):

50 mg - AUST R 241755

200 mg - AUST R 226821

300 mg - AUST R 226818

400 mg - AUST R 226800

#### **Sponsor**

Medis Pharma Pty Ltd  
1002/53 Walker St  
North Sydney NSW 2060

#### **Distributor**

Apotex Pty Ltd  
16 Giffnock Avenue  
Macquarie Park NSW 2113

This leaflet was last updated in June 2016.