

# TEVATIAPINE XR®

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

### 1. Why am I using TEVATIAPINE XR?

TEVATIAPINE XR contains the active ingredient quetiapine fumarate. TEVATIAPINE XR is used to help correct chemical imbalances in the brain. It is used to treat conditions such as: Bipolar disorder, recurrent major depressive disorder, generalised anxiety disorder and schizophrenia. For more information, see Section [1. Why am I using TEVATIAPINE XR?](#) in the full CMI.

### 2. What should I know before I use TEVATIAPINE XR?

Do not use if you have ever had an allergic reaction to quetiapine or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use TEVATIAPINE XR?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with TEVATIAPINE XR and affect how it works. A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use TEVATIAPINE XR?

- 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.
- TEVATIAPINE XR should be taken once a day, at approximately the same time each day. It should be swallowed whole with a full glass of water. Do not split, chew or crush the tablets. It should be taken without food.

More instructions can be found in Section [4. How do I use TEVATIAPINE XR?](#) in the full CMI.

### 5. What should I know while using TEVATIAPINE XR?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using TEVATIAPINE XR.</li><li>• Call your doctor straight away if you have any suicidal thoughts or mental/mood changes.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not stop using this medicine suddenly.</li><li>• Do not take any medicines that cause drowsiness while you are taking it, unless recommended by your doctor.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• TEVATIAPINE XR may cause dizziness or sleepiness in some people. Make sure you know how you react to it before you drive a car or operate machinery.</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>• Combining quetiapine and alcohol can make you more sleepy or dizzy. Your doctor may suggest you avoid alcohol while you are being treated with it.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Keep it in a cool dry place where the temperature stays below 25°C.</li><li>• Store your tablets in their original packaging to protect from moisture.</li></ul>

For more information, see Section [5. What should I know while using TEVATIAPINE XR?](#) in the full CMI.

### 6. Are there any side effects?

Common, less serious side effects: weight gain, increased appetite, upset stomach, constipation, dry mouth, blurred vision, feeling sleepy, irritability and abnormal dreams, nightmares.

Serious side effects: symptoms of high sugar levels and widespread skin rash that may include blistering or peeling of the skin, often accompanied by flu like symptoms. Combination of fever, very marked drowsiness, muscle stiffness, marked increase in blood pressure or heartbeats and reduced consciousness (a disorder called “neuroleptic malignant syndrome”)

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# TEVATIAPINE XR®

Modified release tablet

**Active ingredient(s):** Quetiapine fumarate

## Consumer Medicine Information (CMI)

This leaflet provides important information about using TEVATIAPINE XR. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using TEVATIAPINE XR.**

**Where to find information in this leaflet:**

- [1. Why am I using TEVATIAPINE XR?](#)
- [2. What should I know before I use TEVATIAPINE XR?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use TEVATIAPINE XR?](#)
- [5. What should I know while using TEVATIAPINE XR?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I using TEVATIAPINE XR?

**TEVATIAPINE XR contains the active ingredient quetiapine fumarate.** TEVATIAPINE XR belongs to a group of medicines called antipsychotics.

**TEVATIAPINE XR is used to help correct chemical imbalances in the brain. It is used to treat conditions such as:**

- Bipolar disorder, an illness of 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 behavior.

You may find it helpful to tell a friend or relative that you are suffering from these symptoms, and ask them to read this leaflet. You might ask them to tell you if they think your symptoms are getting worse, or if they are worried about any other changes in your behaviour.

## 2. What should I know before I use TEVATIAPINE XR?

### Warnings

**Do not use TEVATIAPINE XR if:**

- you are allergic to quetiapine, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

**Check with your doctor if you:**

- have any other 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 modified release tablets.
  - 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.
  - history of alcohol or drug abuse.
- take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

### Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

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.

## Children

Quetiapine modified release tablets are not recommended for use in children. There is not enough information on its effects in children.

## Elderly

Quetiapine, as with other antipsychotic medicines, is recommended for use with caution in the elderly and is not approved for treatment of dementia and behavioural disturbances. In clinical studies with this group of medicines for the treatment of dementia and behavioural disturbances in the elderly, have suggested an increased risk of cardiovascular adverse events including stroke, and increased mortality risk for elderly patients has been reported.

## 3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

**Some medicines may interfere with TEVATIAPINE XR and affect how it works.**

- 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)
- medicines that have anticholinergic (muscarinic) effects

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect TEVATIAPINE XR.**

## 4. How do I use TEVATIAPINE XR?

### 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 modified release tablets are 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 quetiapine modified release 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.
- Your doctor may have switched your treatment from quetiapine immediate release tablets to quetiapine

modified release tablets. Your doctor will generally prescribe you a once daily dose of quetiapine modified release tablets, 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.

- Follow the instructions provided and use TEVATIAPINE XR until your doctor tells you to stop.

### When to take TEVATIAPINE XR

- TEVATIAPINE XR should be taken once a day, at approximately the same time each day.
- It should be swallowed whole with a full glass of water. Do not split, chew or crush the tablets.
- It should be taken without food

### If you forget to use TEVATIAPINE XR

TEVATIAPINE XR should be used regularly at the same time each day. If you miss your dose at the usual time, take it as soon as you remember, and then go back to taking your medicine as you would normally.

**If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.**

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

### If you use too much TEVATIAPINE XR

If you think that you have used too much TEVATIAPINE XR, you may need urgent medical attention.

#### You should immediately:

- phone the Poisons Information Centre **by calling 13 11 26**, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## 5. What should I know while using TEVATIAPINE XR?

### Things you should do

- 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.
- Before your doctor starts you on quetiapine modified release 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.
- If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking it.
- If you become pregnant while taking it, tell your doctor immediately.
- 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.

### Call your doctor straight away 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.

Remind any doctor, dentist or pharmacist you visit that you are using TEVATIAPINE XR.

### Things you should not do

- Do not stop using this medicine suddenly.
- Do not take it to treat any other complaints unless your doctor tells you to.
- Do not give this medicine to anyone else, even if their symptoms seem similar or they have the same condition as you.
- Do not take any medicines that cause drowsiness while you are taking it, unless recommended by your doctor.

### Things to be careful of

- 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.
- Quetiapine may affect the way your body reacts to temperature changes. 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 be affected by grapefruit juice. Avoid drinking large quantities of grapefruit juice.

### Driving or using machines

#### Be careful before you drive or use any machines or tools until you know how TEVATIAPINE XR affects you.

TEVATIAPINE XR may cause dizziness or sleepiness in some people. 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.

### Drinking alcohol

#### Tell your doctor if you drink alcohol.

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

### Looking after your medicine

- Keep your tablets in the blister pack until it is time to take them.
- Keep it in a cool dry place where the temperature stays below 25°C.

- Store your tablets in their original packaging to protect from moisture.

Follow the instructions in this leaflet on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

### Keep it where young children cannot reach it.

### Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Less serious side effects

Less serious side effects	What to do
<p><b>Gut related:</b></p> <ul style="list-style-type: none"><li>• weight gain, increased appetite</li><li>• dry mouth</li><li>• upset stomach, constipation, indigestion, vomiting (mainly in elderly or children)</li></ul> <p><b>Sleep related:</b></p> <ul style="list-style-type: none"><li>• feeling sleepy</li><li>• feeling weak</li><li>• abnormal dreams, nightmares</li><li>• irritability</li></ul> <p><b>Heart or Lung related:</b></p> <ul style="list-style-type: none"><li>• shortness of breath, difficulty in breathing and/or tightness in the chest</li><li>• fast or irregular heartbeats (palpitations)</li></ul> <p><b>Other:</b></p> <ul style="list-style-type: none"><li>• swelling of the hands, ankles or feet</li><li>• runny or stuffy nose (particularly in children)</li><li>• blurred vision</li><li>• muscle pain or swelling or weakness</li></ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

### Serious side effects

Serious side effects	What to do
<p><b>Related to the reproductive system:</b></p> <ul style="list-style-type: none"><li>• breast enlargement, unusual secretion of breast milk</li></ul>	<p><b>Call your doctor straight away, or go</b></p>

Serious side effects	What to do
<ul style="list-style-type: none"> <li>• long-lasting and painful erections</li> </ul> <p><b>Symptoms of high sugar levels:</b></p> <ul style="list-style-type: none"> <li>• passing large amounts of urine</li> <li>• excessive thirst</li> <li>• increase in appetite with a loss of weight</li> <li>• feeling tired, drowsy and weak</li> <li>• depressed, irritable and generally unwell</li> </ul> <p><b>Heart and Body temperature:</b></p> <ul style="list-style-type: none"> <li>• rapid heart beat</li> <li>• a sudden increase in body temperature, with sweating, or a fast heart beat</li> </ul> <p><b>Skin, immune and infection related:</b></p> <ul style="list-style-type: none"> <li>• widespread skin rash that may include blistering or peeling of the skin, often accompanied by flu like symptoms, fever, swelling of the face and/or swollen lymph nodes (painful, warm, or red lump under your skin - often under your chin, on your neck, groin, armpit or behind your ear). These symptoms may also be associated with changes in your blood (eg white blood cell increase, as sometimes seen in allergic reactions) or liver function. These are some of the symptoms of potentially life-threatening conditions called Stevens-Johnson Syndrome (SJS), toxic epidermal necrolysis (TEN) and drug reaction with eosinophilia and systemic symptoms (DRESS).</li> <li>• severe allergic reaction (may include severe difficulty in breathing, shock, swelling of the face, lips, tongue or other parts of the body, skin rash, hayfever, or you may feel faint)</li> <li>• signs of frequent infections such as fever, chills, sore throat or mouth ulcers</li> <li>• flat and red skin lesions or substantial hemorrhages under the skin (purpura)</li> </ul> <p><b>Muscle related:</b></p> <ul style="list-style-type: none"> <li>• difficulty in speaking</li> <li>• difficulty swallowing</li> <li>• abnormal muscle movements, including difficulty starting muscle movements, shaking, restlessness or muscle stiffness without pain.</li> <li>• 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</li> </ul>	<p><b>straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

Serious side effects	What to do
<ul style="list-style-type: none"> <li>• Combination of fever, very marked drowsiness, muscle stiffness, marked increase in blood pressure or heartbeats and reduced consciousness (a disorder called “neuroleptic malignant syndrome”)</li> </ul> <p><b>Gut related:</b></p> <ul style="list-style-type: none"> <li>• 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 symptoms of pancreatitis.</li> </ul> <p><b>Blood or liver function:</b></p> <ul style="list-style-type: none"> <li>• changes in 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.</li> <li>• bleeding or bruising more easily than normal</li> </ul> <p><b>Brain/mental alertness:</b></p> <ul style="list-style-type: none"> <li>• falling, feeling dizzy or faint on standing up</li> <li>• very marked drowsiness</li> <li>• reduced consciousness</li> <li>• fainting (particularly in children)</li> <li>• fits (seizures)</li> </ul>	

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

#### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

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

#### What TEVATIAPINE XR contains

<b>Active ingredient (main ingredient)</b>	quetiapine fumarate
<b>Other ingredients (inactive ingredients)</b>	Microcrystalline cellulose Sodium citrate Magnesium stearate

Hypromellose
Macrogol 400
Polysorbate 80
Titanium dioxide (E171)
Iron oxide red (E172 – 50 mg, 200 mg and 300 mg tablets)
Iron oxide yellow (E172 – 50 mg, 200 mg and 300 mg)
Iron oxide black (50 mg and 300 mg tablets)

**Do not take this medicine if you are allergic to any of these ingredients.**

TEVATIAPINE XR tablets do not contain gluten or lactose.

#### **What TEVATIAPINE XR looks like**

TEVATIAPINE XR tablets are biconvex oblong shaped and are debossed with "Q" and the strength on one side, and plain on the other. Tablet colouring is as follows:

- 50 mg – brown (Aust R 249712)
- 150 mg – white (Aust R 249752)
- 200 mg – yellow (Aust R 249772)
- 300 mg – light yellow (Aust R 249792)
- 400 mg – white (Aust R 249812)

All strengths are available in packs of 60 tablets.

#### **Who distributes TEVATIAPINE XR**

Teva Pharma Australia Pty Ltd

Level 1, 37 Epping Road

Macquarie Park NSW 2113

This leaflet was updated in January 2022.