

SYQUET 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 SYQUET XR?

SYQUET XR contains the active ingredient quetiapine. SYQUET 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. Your doctor may have prescribed this for something else. For more information, see Section [1. Why am I using SYQUET XR?](#) in the full CMI.

2. What should I know before I use SYQUET 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 SYQUET XR?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with SYQUET 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 SYQUET XR?

Quetiapine modified release tablets should be swallowed whole (not split, chewed or crushed) without food. Your doctor will explain the dose you need. More instructions can be found in Section [4. How do I use SYQUET XR?](#) in the full CMI.

5. What should I know while using SYQUET XR?

Things you should do	- Remind any doctor, dentist or pharmacist you visit that you are using SYQUET XR, particularly if you are about to start any new medicine or need surgery with general anaesthetic. - Tell your doctor, or go to the nearest hospital, if you have any suicidal thoughts or other mood changes. - Tell your doctor immediately if you become pregnant while taking it.
Things you should not do	- Do not stop taking this medicine, or change the dosage, without checking with your doctor. - Do not take any other medicines that cause drowsiness while you are taking it, unless recommended - Do not get over-heated or dehydrated or get too cold in cool weather as SYQUET XR may affect the way your body reacts to temperature changes.
Driving or using machines	Be careful driving or operating machinery until you know how SYQUET XR affects you. It can make some people dizzy or sleepy.
Drinking alcohol	Your doctor may suggest you avoid alcohol while you are being treated with this medicine.
Looking after your medicine	Keep tablets in their original packaging in a cool dry place, where the temperature stays below 25°C.

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

6. Are there any side effects?

Tell your doctor immediately if you; have abnormal muscle movements, uncontrolled movements of the tongue, mouth, cheeks or jaw, sudden increase in body temperature, with sweating, or a fast heartbeat, bleeding or bruising more easily than normal, drowsiness, reduced consciousness, fits (seizures), long-lasting and painful erections, fainting (particularly in children), skin rash that may include blistering or peeling of the skin, flu like symptoms, fever, swelling of the face and/or swollen lymph nodes, 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), chills, sore throat or mouth ulcers, severe upper stomach pain, often with nausea and vomiting, combination of fever, very marked drowsiness, muscle stiffness, marked increase in blood pressure or heartbeats.

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.

SYQUET XR

Active ingredient(s): *quetiapine*

Consumer Medicine Information (CMI)

This leaflet provides important information about using SYQUET 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 SYQUET XR.**

Where to find information in this leaflet:

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

1. Why am I using SYQUET XR?

SYQUET XR contains the active ingredient quetiapine.

SYQUET XR belongs to a group of medicines called antipsychotics.

SYQUET 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).
- 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.
- Generalised anxiety disorder, where patients have excessive anxiety and worry.
- Schizophrenia, an illness with disturbances in thinking, feelings and behaviour.

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

2. What should I know before I use SYQUET XR?

Warnings

Do not use SYQUET XR if:

- You are allergic to quetiapine or any of the ingredients listed at the end of this leaflet. This medicine contains lactose. Always check the ingredients to make sure you can use this medicine.
- SYQUET XR is not recommended for use in children. There is not enough information on its effects in children.
- SYQUET XR, as with other anti-psychotic 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.

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.

Check with your doctor if you:

Have or have had 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 SYQUET XR.
- 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

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.

Advise your doctor if you 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

If you become pregnant while taking this medicine, tell your doctor immediately. It is not known if it is safe for you to take while you are pregnant. However, if you need to take it during

your pregnancy, the doctor will explain the risks and benefits of taking it.

Check with your doctor if you intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed. It is recommended that you do not breastfeed while taking it, as it may pass into breast milk. Ask your doctor for more information.

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 SYQUET XR and affect how it works.

Medicines that may increase the effect of SYQUET XR include:

- Medicines for fungal infections such as ketoconazole

Medicines that may reduce the effect of SYQUET XR include:

- Phenytoin or carbamazepine medicines for epilepsy
- Thioridazine – an antipsychotic medicine
- Rifampicin – an antibiotic
- Glucocorticoids – medicines used to treat inflammation

Other medicines that may affect the dose you need to take of SYQUET XR include:

- 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
- Erythromycin – an antibiotic
- Medicines used to treat Parkinson's disease
- Medicines for Human Immunodeficiency Virus (HIV)
- Medicines that have anti-cholinergic (muscarinic) effects
- Stimulants such as amphetamines

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

4. How do I use SYQUET XR?

How much to take/use

- Follow the instructions provided by your doctor and use SYQUET XR until your doctor tells you to stop. Instructions may differ from information included in this leaflet.
- SYQUET XR tablets should be swallowed whole (not split, chewed or crushed) and taken without food.
- SYQUET XR 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 (e.g. 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 SYQUET XR tablets. Your doctor will generally prescribe you a once daily dose of SYQUET XR, 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.

If you forget to use SYQUET XR

SYQUET XR should be used regularly at the same time each day.

If you miss your dose and 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 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 use too much SYQUET XR

If you think that you have used too much SYQUET 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 SYQUET XR?

Things you should do

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

If you are about to start 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 plan to have surgery that needs a general anaesthetic, tell your doctor/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 medical appointments so that your progress can be checked. Your doctor will check your progress and may want to take some tests (e.g. blood tests, blood pressure, weight or height measurements) from time to time. These tests may help to prevent side effects.

Things you should 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 SYQUET XR you take each day before stopping completely.
- 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.
- Do not take it if you are lactose intolerant, this medicine contains lactose.

Driving or using machines

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

SYQUET XR may cause dizziness in some people

Drinking alcohol

Tell your doctor if you drink alcohol.

Combining SYQUET XR 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

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

Store below 25°C 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
• 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)	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
• difficulty swallowing • falling, feeling dizzy or faint on standing up • difficulty in speaking • rapid heartbeat • 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	Tell your doctor as soon as possible if you notice any of these serious side effects.

Very serious side effects

Very serious side effects	What to do
• 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 heartbeat • bleeding or bruising more easily than normal • very marked drowsiness • reduced consciousness • fits (seizures) • long-lasting and painful erections • fainting (particularly in children)	Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Very serious side effects	What to do
- Widespread skin rash that may include blistering or peeling of the skin, often accompanied by flu like symptoms and 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 (e.g. 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). - 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). These are symptoms of pancreatitis. - Combination of fever, very marked drowsiness, muscle stiffness, marked increase in blood pressure or heartbeats and reduced consciousness (a disorder called “neuroleptic malignant syndrome”).	Tell your doctor as soon as possible if you notice any of these serious side effects.
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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. 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 SYQUET XR contains

Active ingredient (main ingredient)	Quetiapine
Other ingredients (inactive ingredients)	Lactose monohydrate Hypromellose Sodium chloride Povidone Purified talc Magnesium stearate Microcrystalline cellulose
Potential allergens	Lactose monohydrate

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

What SYQUET XR looks like

SYQUET XR modified release tablets 50 mg:

Peach colored, round shaped, biconvex film coated tablets, debossed with 'Q50' on one side and plain on the other in blister packs [PVC/PVdC-Alu and Alu-Alu] of 60s

(AUST R 346817)

SYQUET XR modified release tablets 150 mg:

White to off white, capsule shaped, biconvex, film coated tablets, debossed with 'AB2' on one side and plain on other side, in blister packs [PVC/PVdC-Alu and Alu-Alu] of 60s

(AUST R 346821)

SYQUET XR modified release tablets 200 mg:

Yellow coloured, round shaped, biconvex film coated tablets, debossed with 'I2' on one side and plain on the other in blister packs [PVC/PVdC-Alu] of 60s

(AUST R 346828)

SYQUET XR modified release tablets 300 mg:

Light yellow coloured, round shaped, biconvex film coated tablets, debossed with 'Q300' on one side and plain on the other, in blister packs [PVC/PVdC-Alu] of 60s

(AUST R 346829)

SYQUET XR modified release tablets 400 mg:

White coloured, round shaped, biconvex, film coated tablets debossed with 'I4' on one side and plain on the other, in blister packs [PVC/PVdC-Alu] of 60s

(AUST R 346812)

Who distributes SYQUET XR

Accord Healthcare Pty Ltd
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Australia

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This leaflet was prepared in October 2020.