

Amisulpride Sandoz Pharma

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 take Amisulpride Sandoz Pharma?

Amisulpride Sandoz Pharma contains the active ingredient amisulpride. Amisulpride Sandoz Pharma is used to the symptoms of schizophrenia, a condition which affects the way you think, feel or act.

For more information, see Section [1. Why am I take Amisulpride Sandoz Pharma?](#) in the full CMI.

2. What should I know before I take Amisulpride Sandoz Pharma?

Do not take if you have ever had an allergic reaction to amisulpride 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 take Amisulpride Sandoz Pharma?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Amisulpride Sandoz Pharma 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 take Amisulpride Sandoz Pharma?

- Tablets should be taken once or twice a day as advised by your doctor. Your doctor will tell you how many tablets to take.
- Swallow the tablets whole with a full glass of water.
- Your doctor may increase or decrease your dose depending on your condition.

More instructions can be found in Section [4. How do I take Amisulpride Sandoz Pharma?](#) in the full CMI.

5. What should I know while taking Amisulpride Sandoz Pharma?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using Amisulpride Sandoz Pharma.• Tell your doctor if you are starting any other new medicine.• Tell your doctor if your mood changes, including feelings of depression or thoughts of self-harm.
Things you should not do	<ul style="list-style-type: none">• Do not stop taking this medicine or change your dose unless your doctor tells you too.• Do not give this medicine to anyone else, or take it for other complaints.
Driving or using machines	<ul style="list-style-type: none">• As this medicine may cause dizziness or drowsiness, be careful driving or operating machinery until you know how this medicine affects you.• Be careful taking antihistamines, sleeping tablets or tablets to relieve pain while taking Amisulpride Sandoz Pharma, as you may experience increased drowsiness which can affect your ability to drive or operate machines.
Drinking alcohol	<ul style="list-style-type: none">• The effects of alcohol could be made worse while taking this medicine.• It is NOT recommended that you drink alcohol while taking Amisulpride Sandoz Pharma.
Looking after your medicine	<ul style="list-style-type: none">• Keep your tablets in a cool dry place where the temperature stays below 25°C.

For more information, see Section [5. What should I know while taking Amisulpride Sandoz Pharma?](#) in the full CMI.

6. Are there any side effects?

Common side effects are drowsiness, weight gain, dizziness, increased appetite, nausea, vomiting, constipation, dry mouth, blurred vision, insomnia, anxiety, agitation and problems with orgasm.

Serious side effects include muscle twitching, abnormal movements mainly of the face or tongue, fever, unexplained infections faster breathing, sweating, muscle stiffness, yellowing of the skin and eyes, light coloured bowel motions, dark coloured urine.

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.

Amisulpride Sandoz Pharma

Amisulpride: (ami-sulp-ride)

Consumer Medicine Information (CMI)

This leaflet provides important information about using [medicine name]. **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 [medicine name].**

Where to find information in this leaflet:

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

1. Why am I taking Amisulpride Sandoz Pharma?

Amisulpride Sandoz Pharma contains the active ingredient **amisulpride**. Amisulpride Sandoz Pharma is an antipsychotic medication.

Amisulpride Sandoz Pharma is used to treat symptoms of schizophrenia.

Schizophrenia is a condition which affects the way you think, feel or act. It may cause symptoms such as hallucinations (e.g. hearing, seeing or sensing things which are not there), delusions, unusual suspiciousness, emotional, social withdrawal, depression, or anxiety.

2. What should I know before I take Amisulpride Sandoz Pharma?

Warnings

Do not take Amisulpride Sandoz Pharma if:

- you are allergic to amisulpride, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can take this medicine.
Signs of an allergic reaction may include a skin rash, itching, shortness of breath or swelling of the face, lips or tongue.
- you have tumors or cancer in the breast, adrenal glands (phaeochromocytoma), or pituitary gland (near the base of the brain).
- you are a child that has not gone through puberty.
- you are breast feeding or plan to breast feed.

- if you have liver disease
- if you are taking any of the following medicines:
 - medicines used to treat irregular heart rhythm such as quinidine, disopyramide, amiodarone and sotalol
 - cisapride, used to treat reflux
 - antibiotics including sparfloxacin or pentamidine, or antibiotics injected into the vein including erythromycin
 - levodopa, a medicine used in Parkinson's disease
 - thioridazine or sultopride, antipsychotic medicines
 - methadone, a medicine used to treat pain or addiction
 - intravenous vincamine used to increase blood flow to the brain or to reduce tumors.
 - bepridil, used to treat angina
 - halofantrine, used to treat malaria and given as an injection into the vein

Do not take Amisulpride Sandoz Pharma if the packaging is torn or damaged or the expiry date on the pack has passed.

Check with your doctor if you:

- have had an allergic reaction to other medicines
- are elderly or under 18 years of age
- have kidney or liver disease, Parkinson's disease or have previously had seizures
- have problems with the heart and blood vessels
- a history of blood clots
- have lactose intolerance
- have hyperglycaemia (high sugar levels in the blood) or a family history of diabetes. Your doctor may recommend monitoring your blood sugar levels while you are taking Amisulpride Sandoz Pharma
- suffer from dementia
- have mental/mood changes or suicidal thoughts. Patients (and care givers of patients) need to monitor for any worsening of their condition and/or the development of thoughts of suicide, suicidal behaviour or thoughts of harming themselves. Seek medical advice immediately if these symptoms present
- have risk factors for stroke
- have a history or family history of breast cancer
- have a history of sleep apnoea

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. The use of this medicine in pregnancy is not recommended and requires careful monitoring.

Talk to your doctor if you are breastfeeding or intend to breastfeed. This medicine should not be used in breast feeding.

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 and Amisulpride Sandoz Pharma may interfere with each other. These include:

- medicines used to treat irregular heart rhythm such as quinidine, disopyramide, amiodarone and sotalol
- other medicines used to treat heart problems such as diltiazem, verapamil, digoxin and drugs known as beta blockers (e.g. propranolol)
- intravenous amphotericin B, an anti-fungal given by injection into the veins
- other antipsychotics such as thioridazine, clozapine, chlorpromazine, trifluoperazine, pimozide, haloperidol, imipramine and lithium
- diuretics, e.g. furosemide
- stimulant laxatives, e.g. bisacodyl
- glucocorticosteroids, e.g. dexamethasone, hydrocortisone
- diagnostics drug such as tetracosactides
- medicines taken for anxiety or to help you sleep, e.g. diazepam, temazepam
- medicines taken for depression, e.g. fluoxetine, citalopram
- some strong pain killers or drugs to reduce sensation, e.g. morphine, oxycodone
- antihistamines, medicines to treat allergies, which cause drowsiness, e.g. chlorphenamine
- some medicines taken to control blood pressure, e.g. clonidine, chlorothiazide.
- guanfacine used to treat attention disorders

These medicines may be affected by Amisulpride Sandoz Pharma or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Be careful while taking antihistamines, sleeping tablets or tablets to relieve pain while taking this medicine.

Amisulpride Sandoz Pharma can increase drowsiness caused by medicines affecting your nervous system.

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

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

3. How do I take Amisulpride SANDOZ CP?

How much to take

- Your doctor will tell you how many tablets you need to take each day and when to take them. This depends on your condition and whether or not you are taking any other medicines. The dosage is adjusted for each individual and can range from 50 mg a day up to 800 mg a day. In some cases your doctor may increase the dose to 1200 mg a day.
- Your doctor may increase or decrease your dose depending on your condition or if you are elderly.
- Do not take more than the dose your doctor has recommended.
- Swallow the tablets whole with a full glass of water.

When to take Amisulpride Sandoz Pharma

- Tablets should be taken once or twice a day as advised by your doctor.
- Tablets should preferably be taken before meals. Take your prescribed dose at about the same time each day.

If you forget to take Amisulpride Sandoz Pharma

Amisulpride Sandoz Pharma should be taken regularly at the same time each day. If you miss your dose at the usual time, take your dose as soon as you remember.

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 take too much Amisulpride Sandoz Pharma

If you think that you have taken too much Amisulpride Sandoz Pharma 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. If you take too much, the most common signs are drowsiness and slurred speech.

4. What should I know while taking Amisulpride Sandoz Pharma?

Things you should do

Continue taking Amisulpride Sandoz Pharma for as long as your doctor tells you too, even if you feel better. It will help you stay well.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking this medicine.

Visit your doctor regularly so they can check on your progress.

Call your doctor straight away if you:

- your mood changes
- you become depressed or more depressed, irritable, agitated or aggressive
- you have had thoughts or attempts of self-harm, suicide or death

Occasionally, the symptoms of depression may include thoughts of suicide or self-harm. These symptoms may continue to get worse during the early stages of treatment until 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 taking Amisulpride Sandoz Pharma.

Things you should not do

- Do not drive or operate machinery until you know how Amisulpride Sandoz Pharma affects you.
- Do not take Amisulpride Sandoz Pharm to treat any other complaints unless your doctor tells you to.
- Do not give your medicine to anyone else, even if they have the same condition as you.
- It is important that you do NOT stop taking Amisulpride Sandoz Pharma unless your doctor tells you. Do not stop taking this medicine just because you feel better.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Amisulpride Sandoz Pharma affects you.

Amisulpride Sandoz Pharma may cause dizziness or drowsiness in some people

Drinking alcohol

Tell your doctor if you drink alcohol.

The effects of alcohol could be made worse while taking this medicine. It is NOT recommended that you drink alcohol while taking Amisulpride Sandoz Pharma.

Looking after your medicine

- Keep your tablets below 25°C.

Follow the instructions in the carton on how to take care of your medicine properly. Keep your tablets in the pack until it is time to take them.

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 take this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not take this medicine after the expiry date.

5. 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
<ul style="list-style-type: none">• drowsiness, dizziness• increased appetite, weight gain• nausea, vomiting• constipation• dry mouth• blurred vision• insomnia• anxiety, agitation• problems with orgasm	Speak to your doctor if you have any of these less serious side effects and they worry you.

These are the most common side effects.

Some elderly people may experience side effects such as drowsiness, confusion, dizziness and unsteadiness, which may increase the risk of a fall.

Rare side effects include sleep walking and sleep eating and restless legs syndrome, which causes leg movements typically at night.

Some people may feel dizzy in the early stages of treatment, especially when getting up from a lying or sitting position. This side effect usually passes after a few days.

Sometimes trembling, noticeable muscle stiffness or spasm, slowness of movement, excess saliva, restlessness, an overwhelming urge to move and either distress or movements such as pacing, swinging of the legs while

seated, rocking from foot to foot, or both can occur. Is this occurs, your doctor may need to reduce your dose or prescribe an additional medicine.

High blood sugar has been reported in some patients taking this medicine. Symptoms include passing more urine than normal, persistent thirst, increased appetite with a loss in weight and weakness.

Some people experience increased sensitivity to the sun or sunburn which may occur more quickly than normal.

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">muscle twitching, abnormal movements mainly of the face, eyes or tonguefever, unexplained infectionsfaster breathingsweatingmuscle stiffnessyellowing of the skin and eyes, also called jaundicelight coloured bowel motionsdark coloured urineconfusion, seizures, heart palpitations, shortness of breath, chest pain	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.

After prolonged use in women, medicines of this type can cause breast pain, milk secretion, an absence of their monthly period and changes in the regularity of their periods.

Tell your doctor if your monthly periods are absent for six months or more.

After prolonged use in men, medicines of this type can cause breast enlargement or impotence.

Incidences of abnormal liver function have occasionally been reported.

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.

6. Product details

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

What Amisulpride Sandoz Pharma contains

Active ingredient (main ingredient)	amisulpride
Other ingredients (inactive ingredients)	microcrystalline cellulose, hypromellose, magnesium stearate, lactose monohydrate and sodium starch glycollate A.
Potential allergens	The tablets do not contain gluten, sucrose, tartrazine or any other azo dyes.

Amisulpride Sandoz Pharma tablets contain sugars as lactose monohydrate.

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

What Amisulpride Sandoz Pharma looks like

Amisulpride Sandoz Pharma tablets comes in 3 different strengths:

- Amisulpride Sandoz Pharma 100 - White, round, flat tablets embossed MC on one side
- Amisulpride Sandoz Pharma 200 - White, round, flat scored on one side tablets
- Amisulpride Sandoz Pharma 400 - White, biconvex, capsule shaped tablets, scored on both sides.

The 50mg, 100 mg, 200 mg and 400 mg strengths are available in pack sizes of 30, 60 and 90 tablets.

Amisulpride Sandoz Pharma 100mg tablet- AUST R 234708

Amisulpride Sandoz Pharma 200mg tablet- AUST R 234703

Amisulpride Sandoz Pharma 400mg tablet- AUST R 234704

Who supplies Amisulpride Sandoz Pharma

Southern Cross Pharma Pty Ltd
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Hawthorn, VIC, 3122
Australia

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