

AMISULPRIDE SANDOZ PHARMA

contains the active ingredient amisulpride

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about AMISULPRIDE SANDOZ PHARMA.

It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking AMISULPRIDE SANDOZ PHARMA against the benefits they expect it will have for you.

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

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

What AMISULPRIDE SANDOZ PHARMA is used for

AMISULPRIDE SANDOZ PHARMA is used to treat symptoms of schizophrenia.

Schizophrenia is a condition which affects the way you think, feel and/or act.

Schizophrenia may cause symptoms such as hallucinations (eg hearing, seeing or sensing things which are not there), delusions, unusual suspiciousness, emotional and social withdrawal. People with schizophrenia may also feel depressed, anxious or tense.

AMISULPRIDE SANDOZ PHARMA belongs to a group of medicines called antipsychotics.

Your doctor may have prescribed AMISULPRIDE SANDOZ PHARMA for another reason.

Ask your doctor if you have any questions about why AMISULPRIDE SANDOZ PHARMA has been prescribed for you.

AMISULPRIDE SANDOZ PHARMA must not be taken by children up to the age of puberty. There is limited information on the use of AMISULPRIDE SANDOZ PHARMA in adolescents and its use is not recommended from puberty to the age of 18 years. If you are not yet 18 years of age, ask your doctor if AMISULPRIDE SANDOZ PHARMA is right for you.

AMISULPRIDE SANDOZ PHARMA is available only with a doctor's prescription.

Before you take AMISULPRIDE SANDOZ PHARMA

When you must not take it

Do not take AMISULPRIDE SANDOZ PHARMA if you are allergic to medicines containing amisulpride or any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include skin rash, itching or hives, swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing, wheezing or shortness of breath.

Do not take AMISULPRIDE SANDOZ PHARMA if you are taking the following medicines:

- medicines used to treat irregular heart rhythm such as quinidine, disopyramide, amiodarone and sotalol
- cisapride

- antibiotics such as erythromycin and pentamidine, given as an injection into the veins
- levodopa, a medicine used in Parkinson's disease
- thioridazine, an antipsychotic
- methadone, medicine used to treat pain or addiction.

Do not take AMISULPRIDE SANDOZ PHARMA if you are breastfeeding or planning to breastfeed.

Do not take AMISULPRIDE SANDOZ PHARMA if the expiry date (Exp.) printed on the pack has passed.

Do not take AMISULPRIDE SANDOZ PHARMA if the packaging is torn or shows signs of tampering.

Do not take AMISULPRIDE SANDOZ PHARMA if you have or have had any of the following medical conditions:

- pheochromocytoma, a rare tumour of the adrenal glands which sit near the kidneys
- tumour of the pituitary gland, a small gland at the base of the brain
- breast cancer
- liver disease.

Before you start to take it

Tell your doctor if:

- you have had an allergic reaction to any medicine which have taken previously to treat your current condition.
- any other substances, such as foods, preservatives or dyes
- you suffer from lactose intolerance because AMISULPRIDE SANDOZ PHARMA tablets contain lactose.

Tell your doctor if you are pregnant or plan to become pregnant. AMISULPRIDE SANDOZ PHARMA is not recommended for use in pregnancy.

Your doctor will discuss the risks and benefits of taking AMISULPRIDE SANDOZ PHARMA during pregnancy. Newborns and mothers who have taken AMISULPRIDE SANDOZ PHARMA during pregnancy need to be carefully monitored.

Tell your doctor if you are breastfeeding or wish to breastfeed.

Your doctor will discuss the risks and benefits of taking AMISULPRIDE SANDOZ PHARMA when breastfeeding.

Tell your doctor if you have any medical conditions, especially the following:

- kidney or liver disease, Parkinson's disease or seizures
- problems with the heart and blood vessels
- a history of blood clots
- 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
- 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

- risk factors for stroke
- history or family history of breast cancer.

Your doctor may want to take special care if you have any of these conditions.

If you have not told your doctor about any of the above, tell them before you start taking AMISULPRIDE SANDOZ PHARMA.

Taking other medicines

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

Some medicines may be affected by AMISULPRIDE SANDOZ PHARMA, or may affect how well it works. 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, clonidine, 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, chlorpromazine, trifluoperazine, pimozide, haloperidol, imipramine and lithium
- diuretics
- stimulant laxatives
- glucocorticosteroids
- diagnostics drug such as tetracosactides
- medicines taken for anxiety or to help you sleep
- medicines taken for depression
- some strong pain killers
- antihistamines, medicines to treat allergies, which cause drowsiness
- some medicines taken to control blood pressure.

Your doctor can tell you what to do if you are taking any of these medicines.

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 AMISULPRIDE SANDOZ PHARMA.

How to take AMISULPRIDE SANDOZ PHARMA

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.

Follow all directions given to you by your doctor and pharmacist carefully.

Do not take more than the dose your doctor has recommended.

How to take AMISULPRIDE SANDOZ PHARMA

Swallow the tablets whole with a glass of water.

If you forget to take AMISULPRIDE SANDOZ PHARMA

If you forget to take your medicine, take your dose as soon as you remember.

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.

How long to take AMISULPRIDE SANDOZ PHARMA for

It is important that you do NOT stop taking AMISULPRIDE SANDOZ PHARMA unless your doctor tells you. Do not stop taking AMISULPRIDE SANDOZ PHARMA just because you feel better. It is very important to continue AMISULPRIDE SANDOZ PHARMA because it will help you stay well.

Keep taking AMISULPRIDE SANDOZ PHARMA for as long as your doctor recommends.

If you take too much AMISULPRIDE SANDOZ PHARMA (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much AMISULPRIDE SANDOZ PHARMA. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too much AMISULPRIDE SANDOZ PHARMA, you may feel drowsy and have slurred speech.

While you are taking AMISULPRIDE SANDOZ PHARMA

Things you must do

It is very important to continue taking AMISULPRIDE SANDOZ PHARMA because it will help you stay well.

Before starting any new medicine, tell your doctor or pharmacist that you are taking AMISULPRIDE SANDOZ PHARMA.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking AMISULPRIDE SANDOZ PHARMA.

Tell your doctor immediately, or go to the nearest hospital, if you have any of the following suicidal thoughts or 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
- depressed mood or worsening of depression.

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.

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

Things you must not do

Do not use AMISULPRIDE SANDOZ PHARMA to treat any other conditions unless your doctor tells you to.

Do not give AMISULPRIDE SANDOZ PHARMA to anyone else, even if they have the same condition as you.

Things to be careful of

Be careful driving or operating machinery until you know how AMISULPRIDE SANDOZ PHARMA affects you.

AMISULPRIDE SANDOZ PHARMA may cause drowsiness, dizziness or lightheadedness in some people. If any of these occur, do not drive, operate machinery or do anything else that could be dangerous.

Be careful if you are elderly or unwell. Some people may experience side effects such as drowsiness, confusion, dizziness and unsteadiness, which may increase the risk of a fall.

Be careful when drinking alcohol while taking AMISULPRIDE SANDOZ PHARMA the effects may be worse. It is NOT recommended that you drink alcohol while taking AMISULPRIDE SANDOZ PHARMA.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking AMISULPRIDE SANDOZ PHARMA.

Like all other medicines, AMISULPRIDE may have unwanted side effects in some people. 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 are dose related, so it is important that you never exceed your prescribed dose.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

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:

- drowsiness
- weight gain
- dizziness
- increased appetite
- nausea
- vomiting
- constipation
- dry mouth
- blurred vision
- insomnia
- anxiety
- agitation
- problems with orgasm.

These are the most common side effects of AMISULPRIDE SANDOZ PHARMA.

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 taking AMISULPRIDE SANDOZ PHARMA for 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. This will usually be reduced if your dose of AMISULPRIDE SANDOZ PHARMA is lowered by your doctor or if your doctor prescribes you an additional medicine.

High blood sugar has been reported in patients taking AMISULPRIDE SANDOZ PHARMA. Symptoms of high sugar levels in the blood include passing more urine than normal, persistent excessive thirst, increased appetite with a loss in weight and weakness.

Tell your doctor immediately or go to Accident and Emergency at the nearest hospital if you notice any of the following:

- muscle twitching
- abnormal movements mainly of the face or tongue
- fever
- unexplained infections
- faster breathing
- sweating
- muscle stiffness

If this occurs, stop taking AMISULPRIDE SANDOZ PHARMA immediately and contact your doctor.

After prolonged use in women, medicines of this type can cause:

- breast pain
- milk secretion
- an absence of their monthly period
- 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 been occasionally reported.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything that is making you feel unwell.

After using AMISULPRIDE SANDOZ PHARMA

Storage

Keep AMISULPRIDE SANDOZ PHARMA 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.

Keep your tablets in the blister pack until it is time to take them.

If you take the tablets out of the blister pack they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 30°C. Do not store AMISULPRIDE SANDOZ PHARMA or any other medicine in the bathroom or near a sink.

Do not leave AMISULPRIDE SANDOZ PHARMA in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking AMISULPRIDE SANDOZ PHARMA, or your tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

AMISULPRIDE SANDOZ PHARMA comes in 3 strengths of tablets:

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

Ingredients

The active ingredient in AMISULPRIDE SANDOZ PHARMA is amisulpride.

- each AMISULPRIDE SANDOZ PHARMA 100 tablet contains 100 mg of amisulpride
- each AMISULPRIDE SANDOZ PHARMA 200 tablet contains 200 mg of amisulpride.
- each AMISULPRIDE SANDOZ PHARMA 400 tablet contains 400 mg of amisulpride.

The tablets also contain:

- microcrystalline cellulose
- hypromellose
- magnesium stearate
- lactose
- sodium starch glycollate A.

The tablet contains sugars as lactose.

The tablets do not contain gluten, sucrose, tartrazine or any other azo dyes.

Supplier

Southern Cross Pharma Pty Ltd
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Hawthorn, VIC, 3122
Australia

Australian registration numbers:

AMISULPRIDE SANDOZ PHARMA
100AUST R 234708

AMISULPRIDE SANDOZ PHARMA 200
AUST R 234704

AMISULPRIDE SANDOZ PHARMA 400
AUST R 234703

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