

Sulprix™

contains the active ingredient amisulpride

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about Sulprix.

It does not contain all 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 Sulprix against the benefits expected 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 Sulprix is used for

The name of your medicine is Sulprix. It contains the active ingredient called amisulpride.

Sulprix belongs to a group of medicines called antipsychotics. Sulprix 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.

Your doctor may have prescribed Sulprix for another reason.

Ask your doctor if you have any questions about why Sulprix has been prescribed for you.

Before you take Sulprix

When you must not take it

Do not take Sulprix if you have an allergy to:

- any medicine containing amisulpride
- any of the ingredients listed at the end of this leaflet.

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.

Do not breastfeed if you are taking this medicine.

There is a possibility that your baby may be affected.

Do not take Sulprix if you are taking the following medicines:

- medicines used to treat irregular heart rhythm such as quinidine, disopyramide, amiodarone or sotalol
- cisapride
- antibiotics such as erythromycin and pentamidine, given as an injection into the veins
- levodopa, a medicine used in Parkinson's disease
- thioridazone, an antipsychotic

- methadone, a medicine used to treat pain or addiction.

Do not take Sulprix if you have or have had any of the following medical conditions:

- phaeochromocytoma, 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.

There is no specific information available to recommend the use of Sulprix in children (before the age of puberty).

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have a lactose intolerance.

Sulprix tablets contain lactose.

Tell your doctor if you have or have had any of the following medical conditions:

- kidney or liver disease
- Parkinson's disease or fits (seizures)
- problems with the heart and blood vessels
- hyperglycaemia (high sugar levels in the blood). Your doctor

may recommend monitoring your blood sugar levels while you are taking Sulprix

- dementia (a general decline in all areas of mental ability).

Tell your doctor if you are pregnant or plan to become pregnant.

Your doctor can discuss with you the risks and benefits involved.

Taking other medicines

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

Some medicines and Sulprix may interfere with each other. These include:

- 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
- medicines for depression or to calm emotional and mental illness such as thioridazine, chlorpromazine, trifluoperazine, pimozide, haloperidol, imipramine and lithium
- diuretics
- stimulant laxatives
- glucocorticosteroids
- diagnostic drugs such as tetracosactides
- medicines taken for anxiety or to help your sleep
- some strong painkillers
- antihistamines, medicines to treat allergies, which cause drowsiness
- some medicines taken to control blood pressure.

These medicines may be affected by Sulprix or may affect how well it works. You may need different

amounts of your medicines, or you may need to take different medicines.

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

How to take Sulprix

How much to take

Your doctor will tell you how many Sulprix tablets you should take.

The dosage is adjusted for each individual and can range from 50mg a day up to 800mg a day. In some cases your doctor may increase the dose to 1200mg a day.

Sulprix tablets should be taken once or twice a day as advised by your doctor.

Your doctor may increase or decrease your dose depending on your condition.

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

How to take it

Swallow the tablets whole with a glass of water.

When to take it

Sulprix tablets should preferably be taken before meals.

Take your prescribed dose at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

How long to take it

Do not stop taking Sulprix unless your doctor tells you.

Do not stop taking Sulprix because you feel better.

It is very important to continue taking Sulprix for as long as your doctor tells you to.

This medicine helps control your condition, but does not cure it. It is

important to keep taking your medicine even if you feel well.

If you forget to take it

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 that you missed.

This may increase the chance of you getting an unwanted side effect.

If you take too much (overdose)

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

You may need urgent medical attention.

Symptoms of an overdose may include drowsiness and slurred speech.

While you are taking Sulprix

Things you must do

It is very important to continue taking Sulprix because it will help you stay well.

Tell all doctors, dentists and pharmacists who are treating you that you are taking Sulprix.

While you are taking Sulprix, tell your doctor or pharmacist before you start any new medicine.

Things you must not do

Do not drive or operate machinery until you know how Sulprix affects you.

This medicine may cause drowsiness, dizziness and may affect reaction times in some people. If you have

these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Do not give Sulprix to anyone else.

Your doctor has prescribed it for you and your condition.

Things to be careful of

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.

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 this medicine.

The effects of alcohol could be made worse while taking Sulprix. It is not recommended that you drink alcohol while taking Sulprix.

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

Sulprix can increase drowsiness caused by medicines affecting your nervous system.

Side effects

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

This medicine helps most people with schizophrenia, but it may have unwanted side effects in some people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

If you are over 65 years of age you may have an increased chance of getting side effects.

Do not be alarmed by the following list of side effects.

You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- drowsiness
 - weight gain
 - dizziness, especially when getting up from a lying or sitting position
 - increased appetite
 - constipation
 - dry mouth
 - insomnia
 - anxiety
 - agitation
 - trembling, muscle stiffness or spasm, slowness of movement, excess saliva or restlessness.
- Your doctor may lower your dose or prescribe you an additional medicine.

The above list includes the more common side effects of your medicine.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- signs of allergy such as skin rash, itching or hives, swelling of the face, lips, tongue or other parts of the body; shortness of breath, wheezing or troubled breathing
- uncontrolled and repeated movements of the arms, legs, eyes, mouth, tongue, face and jaw. This may be a sign of tardive dyskinesia, a movement disorder which can be potentially irreversible
- a sudden increase in body temperature, extremely high blood pressure, stiff muscles and severe convulsions. These could be signs of a serious side effect called neuroleptic malignant syndrome
- sudden severe headache, loss of vision, loss of coordination, slurred speech, shortness of breath, chest pain, numbness, heat

or swelling in the arms and legs (thromboembolism).

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

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.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After taking Sulprix

Storage

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 Sulprix tablets in a cool, dry place where the temperature stays below 25°C.

Do not store Sulprix or any other medicine in the bathroom or near a sink. Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep it 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 Sulprix or the tablets have passed their expiry date, ask your pharmacist what to do with the amount left over.

Cnr. Wentworth Park Road & Bay Street
Glebe NSW 2037
Phone: (02) 9298 3999

www.alphapharm.com.au

Product description

What it looks like

Sulprix 100 mg tablet is a white round shaped tablet with 'AMI' breakline '100' on one side and 'G' on the reverse, approximately 7.5 mm in diameter. Each pack contains 30 tablets.

Sulprix 200 mg tablet is a white round shaped tablet with 'AMI' breakline '200' on one side and 'G' on the reverse, approximately 10 mm in diameter. Each pack contains 60 tablets.

Sulprix 400 mg tablet is a white, film-coated, breakable, oblong tablet, embossed with "AS 400" on one side and a break-line on the other side. Each pack contains 60 tablets.

Ingredients

The active ingredient in Sulprix is amisulpride.

The tablets also contain the following inactive ingredients:

lactose

- cellulose microcrystalline
- sodium starch glycolate type A
- hypromellose (E464)
- magnesium stearate.

Sulprix 400 mg tablets also contain the following inactive ingredients in addition to the above mentioned:

- titanium dioxide (E171)
- macrogol 400.

Manufacturer

Sulprix is distributed in Australia by:

Alphapharm Pty Limited

(ABN 93 002 359 739)

Medical Information

Phone: 1800 028 365

Australian registration number:

Sulprix amisulpride 100 mg tablets
Blister Packs AUST R 156044

Sulprix amisulpride 200 mg tablets
Blister Packs AUST R 156048

Sulprix amisulpride 400 mg tablets
Blister Packs AUST R 152460

This leaflet was prepared on

28 January 2010.