

SULPRIX

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 risks and benefits. Your doctor has weighed the risks of you taking SULPRIX 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 the medicine.

You may need to read it again.

What SULPRIX is used for

SULPRIX 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 (e.g. 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 it for another reason.

Ask your doctor if you have any questions about why this medicine 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 take this medicine if you are pregnant or intend to become pregnant.

This medicine is not recommended for use in pregnancy. If you need to take SULPRIX when pregnant, you should discuss the benefits and risks of taking it with your doctor. Newborns of mothers who have taken this medicine during pregnancy need to be carefully monitored.

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
- thioridazine, 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:

- 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

SULPRIX must not be taken by children up to the age of puberty.

Limited information on the use of SULPRIX 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 this medicine is right for you.

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.

If you are not sure whether you should start taking this medicine, talk to your doctor.

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 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
- have or have had 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 SULPRIX
- dementia (a general decline in all areas of mental ability)
- mental/mood changes or suicidal thoughts. Patients (and caregivers 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
- have a history, or family history, of breast cancer.
- have a history of sleep apnoea

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

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 shop.

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

- medicines used to treat irregular heart rhythm such as quinidine, disopyramide, amiodarone and sotalol
- 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, clozapine, trifluoperazine, pimozide, haloperidol, imipramine and lithium
- diuretics
- stimulant laxatives
- glucocorticosteroids

- diagnostic drugs such as tetracosactides
- medicines taken for anxiety or to help you sleep
- anaesthetics (medicine used during surgery)
- medicines taken for depression
- some strong pain killers
- 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

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

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box ask your doctor or pharmacist for help.

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 50 mg a day up to 800 mg a day. In some cases, your doctor may increase the dose to 1200 mg a day.

SULPRIX 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

Take your medicine 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.

SULPRIX should preferably be taken before meals.

How long to take it

Do not stop taking SULPRIX unless your doctor tells you.

Do not stop taking SULPRIX because you feel better.

This medicine helps to 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 are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

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

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

Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.

Make sure you use a contraceptive to prevent pregnancy during treatment with SULPRIX. If you become pregnant whilst taking this medicine, tell your doctor immediately.

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 the effect of the medicine becomes apparent. All mentions of suicide or violence must be taken seriously.

Things you must not do

Do not take SULPRIX 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.

Do not stop taking your medicine or lower the dosage without checking with your doctor.

Things to be careful of

SULPRIX may cause drowsiness in some people.

Be careful driving or operating machinery until you know how SULPRIX affects you.

Some people may have slower reflexes, experience drowsiness or blurred vision while taking SULPRIX.

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

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.

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
- increased appetite
- nausea
- vomiting
- constipation
- dry mouth
- blurred vision
- insomnia
- anxiety
- agitation
- problems with orgasm
- nasal congestion

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

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 SULPRIX 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 SULPRIX is lowered by your doctor or if your doctor prescribes you an additional medicine.

Sleep walking and sleep related behaviour including sleep-related eating disorder have been reported with the use of some antipsychotic medicines, including amisulpride.

High blood sugar has been reported in patients taking SULPRIX. 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.

Some people experience increased sensitivity to the sun or notice symptoms of sunburn (such as redness, itching, swelling, blistering) which may occur faster than normal.

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

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

- sweating
- muscle stiffness
- yellowing of the skin and eyes, also called jaundice
- light coloured bowel motions
- dark coloured urine

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 pack until it is time to take them.

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

Keep your 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 this medicine or the expiry date has passed, ask your pharmacist what to do with the amount left over.

Product description

What it looks like

SULPRIX 100 mg tablets are 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 tablets are 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 tablets are 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

SULPRIX contains either 100 mg, 200 mg or 400 mg of amisulpride as the active ingredient.

The tablets also contain the following inactive ingredients:

- lactose monohydrate
- microcrystalline cellulose
- 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:

- Opadry White Y-1-7000

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SULPRIX tablets contain lactose.

Manufacturer

Alphapharm Pty Ltd

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.mylan.com.au

Australian registration numbers:

AUST R 156044 - 100 mg

AUST R 156048 - 200 mg

AUST R 152460 - 400 mg

This leaflet was prepared in
January 2021.

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