

# NEW ZEALAND CONSUMER MEDICINE INFORMATION

## SULPRIX

*Amisulpride Tablets 100 mg, 200 mg and 400 mg*



### What is in this leaflet

Please read this leaflet carefully before you start taking Sulprix.

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, ask your doctor or pharmacist.**

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

### What Sulprix is used for

Sulprix is used to treat symptoms of schizophrenia, which is a condition that affects the way you think, feel and/or act. Schizophrenia may cause symptoms such as hallucinations, delusions, unusual suspiciousness, emotional and social withdrawal. People with schizophrenia may also feel depressed, anxious or tense.

Sulprix contains the active ingredient amisulpride. It belongs to a group of medicines called antipsychotics.

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.**

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

### 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 Sulprix if you are taking the following medicines:**

- medicines used to treat irregular heart rhythm or heart conditions such as quinidine, disopyramide, amiodarone, sotalol and bepridil
- antibiotics such as erythromycin and pentamidine, given as an injection into the veins or sparfloxacin tablets taken by mouth
- halofantrine, a medicine used to treat malaria
- levodopa, a medicine used in Parkinson's disease
- antipsychotic medicines such as thioridazine and sultopride
- methadone, a medicine used to treat pain or addiction
- cisapride, a medicine used to treat heartburn
- vincamine, an antihypertensive agent.

**Do not take this medicine if you are pregnant.**

It may affect your developing baby if you take it during pregnancy.

**Do not breast-feed if you are taking this medicine.**

The active ingredient in Sulprix passes into breast milk and there is a possibility that your baby may be affected. Breast-feeding is contraindicated in patients taking Sulprix.

**Do not give this medicine to children or adolescents under the age of 18 years.**

Safety and effectiveness in children and adolescents have not been established. From puberty to the age of 18 years Sulprix is not recommended. In children up to puberty, Sulprix should not be used.

**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.

**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 or have had any of the following medical conditions:**

- kidney or liver disease
- Parkinson's disease

- history of seizures
- problems with the heart and blood vessels, low blood pressure
- history of blood clots
- diabetes, history of high blood sugar levels (hyperglycaemia) or family history of diabetes
- dementia
- mood changes or suicidal thoughts
- risk factors for stroke
- history or family history of breast cancer
- restlessness
- unusual muscle tone
- uncontrollable movements
- tumour of pituitary gland
- fever or high body temperature
- muscle rigidity.

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

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

**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 get without a prescription from your pharmacy, supermarket or health food shop.**

You should also tell any healthy professional who is prescribing a new medication for you that you are taking Sulprix.

Some medicines may interfere with Sulprix. These include:

- medicines used to treat irregular heart rhythm such as quinidine, disopyramide, amiodarone, sotalol, digitalis and bepridil
- medicines used to treat heart problems such as diltiazem, verapamil, clonidine, digoxin and beta blockers
- intravenous amphotericin B, an anti-fungal given by injection into the veins
- other antipsychotics medicines such as thioridazine, chlorpromazine, trifluoperazine, pimozide, haloperidol,

- imipramine, lithium and clozapine
- diuretics also known as fluid tablets
- stimulant laxatives
- glucocorticosteroids such as prednisone, dexamethasone and hydrocortisone
- diagnostics drugs such as tetracosactides
- medicines taken for anxiety, depression or to help you sleep, such as barbiturates and benzodiazepine
- some strong pain killers
- some antihistamines, used to treat allergies, which cause drowsiness
- some medicines taken to control blood pressure
- guanfacine, a medicine used to treat attention deficit hyperactivity disorder.

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.

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## **How to take Sulprix**

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**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 tablets you should take. The dose your doctor will prescribe for you will usually be in the range of 400 mg to 800 mg per day.

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

### ***How to take it***

**Swallow the tablets whole with a full glass of water.**

### ***When to take it***

**Take your medicine at about the same times each day.**

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

**Sulprix tablets should be taken once or twice a day preferably before food.**

### ***How long to take it***

**Continue taking your medicine for as long as your doctor tells you.**

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 it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.**

**Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.**

**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.

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## **While you are taking Sulprix**

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### ***Things you must do***

**If you are about to be started on any new medicine, tell 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.**

**If you are going to have surgery, tell the surgeon or anaesthetist**

**that you are taking this medicine.** It may affect other medicines used during surgery.

**If you become pregnant while taking this medicine, tell your doctor immediately.**

**If you are about to have any blood tests, tell your doctor that you are taking this medicine.** It may interfere with the results of some tests.

**Keep all of your doctor's appointments so that your progress can be checked.** Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

**Talk to your doctor or health professional if you have any of the following suicidal thoughts or mood changes:**

- thoughts or talk about death or suicide
- thoughts or talk about self-harm or doing harm to others
- any recent attempts of self-harm
- increase in aggressive behaviour, irritability or agitation
- depressed mood or worsening of depression.

Seek medical advice immediately if these symptoms present. These may be signs of changes or worsening of your condition.

## ***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.**

If you stop taking it suddenly, your condition may worsen or you may have unwanted side effects such as restlessness, unusual muscle tone and uncontrollable twitching, jerking or writhing movements.

If possible, your doctor will gradually reduce the amount you take each day before stopping the medicine completely.

## ***Things to be careful of***

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

This medicine may cause drowsiness and blurred vision in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

**Be careful when drinking alcohol while you are taking this medicine.**

If you drink alcohol, symptoms such as drowsiness and blurred vision may be worse.

**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.

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## **In case of overdose**

**Immediately telephone your doctor or the National Poisons Information Centre (0800 POISON or 0800 764 766) 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, dizziness, lightheadedness, unusual movements and reduced levels of consciousness.

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## **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, but it may have unwanted side effects in a few people.

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

drowsiness, confusion, dizziness and unsteadiness.

**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.**

**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
- dizziness
- headaches
- constipation
- nausea and vomiting
- dry mouth
- trouble sleeping
- weight gain
- nasal congestion
- anxiety
- agitation
- problems with orgasm.

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

**Tell your doctor as soon as possible if you notice any of the following:**

- falling, feeling faint or dizzy on standing up
- blurred vision
- confusion
- unusual movements, including trembling and shaking or the hands and fingers
- restlessness or difficulty sitting still
- stiffness of the arms and legs
- reduced or slow body movement
- difficulty passing urine
- unusual secretion of breast milk
- breast enlargement
- absence of menstrual periods and changes in the regularity of menstrual periods
- symptoms of high sugar levels in the blood (including passing large amounts of urine, excessive thirst, having a dry mouth and skin and weakness). These may indicate the onset or worsening of diabetes.

- Sleep walking or sleep related eating disorder.

The above list includes serious side effects that may require medical attention.

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

- an allergic reaction (symptoms 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)
- seizures, fits or convulsions
- uncontrollable twitching or jerking movements of the tongue, mouth, cheeks, or jaw which may progress to the arms and legs
- sudden increase in body temperature, sweating, fast heartbeat, muscle stiffness, high blood pressure
- changes to heart rate
- sharp chest pain, coughing of blood, or sudden shortness of breath
- weakness or numbness in any part of your body
- severe pain, swelling or discolouration in either of your legs
- unexplained infections or fever
- increased skin sensitivity to light.

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

**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. Tell your doctor if you notice any other effects.

Some of these side effects (for example, changes in blood cell counts, cholesterol or triglyceride level, changes to bone density) can only be found when your doctor does tests from time to time to check your progress.

**Do not be alarmed by this list of possible side effects. You may not experience any of them.**

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## After taking Sulprix

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### 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 on a window sill or in the car.

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 any medicine that is left over.**

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## Product description

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### What it looks like

Sulprix 100 mg tablets are white round shaped tablets with "AMI" breakline "100" on one side and "G" on the other.

Sulprix 200 mg tablets are white round shaped tablets with "AMI" breakline "200" on one side and "G" on the other.

Sulprix 400 mg tablets are white film-coated capsule shaped tablets with "AS 400" on one side and a breakline on the other.

### Ingredients

#### Active ingredient(s):

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

#### Inactive ingredient(s):

Sulprix also contains:

- hypromellose
- lactose monohydrate
- magnesium stearate
- microcrystalline cellulose
- sodium starch glycolate.

Additionally, the 400 mg tablets also contain:

- titanium dioxide
- macrogol.

This medicine does not contain gluten.

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## If you want to know more

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Should you have any questions regarding this product, please contact your pharmacist or doctor.

### **Who supplies this medicine**

Sulprix is supplied in New Zealand by:

Mylan New Zealand Ltd,  
PO Box 11183,  
Ellerslie,  
Auckland  
NEW ZEALAND

Telephone: (09) 579 2792

### **Date of Information**

5 May 2020

(Based on datasheet dated 5 May 2020)