

Consumer Medicine Information**What is in this leaflet**

This leaflet answers some common questions about AMIPRIDE.

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 AMIPRIDE against the benefits they expect it will have for you.

Talk to your doctor or pharmacist if you have any concerns about taking this medicine.

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

What AMIPRIDE 400 is used for

AMIPRIDE belongs to a group of medicines called antipsychotics.

AMIPRIDE is used to treat the symptoms of schizophrenia.

Schizophrenia is a condition which can affect the way you think, feel and 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 AMIPRIDE for another reason.

Ask your doctor if you have any questions about why AMIPRIDE 400 has been prescribed for you.

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

Before you take it**When you must not take it****Do not take amisulpride if:**

- **you have an ALLERGIC REACTION to amisulpride or any of the ingredients listed at the end of this leaflet.**
Signs of an allergic reaction may include a skin rash, itching, shortness of breath or swelling of the face, lips or tongue.
- **you are breastfeeding or plan to breastfeed.**
- **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
- **the packaging is torn or shows signs of tampering or the tablets do not look quite right.**
- **the expiry date on the pack has passed.**

Do not take amisulpride 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

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

There is limited information on the use of amisulpride 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 is right for you.

Before you start to take it

Your doctor must know about all the following before you start to take Amipride 400.

Tell your doctor if:

1. **you have had an allergic reaction to any medicine which you have taken previously to treat your current condition.**
2. **you are pregnant, think you may be pregnant or intend to become pregnant. Amipride 400. is not recommended for use in pregnancy. If you need to take Amipride 400 during pregnancy you should discuss the benefits and risks of taking it with your doctor. Newborns of mothers who have taken Amipride 400 during pregnancy need to be carefully monitored.**
3. **you suffer from lactose intolerance because Amipride 400. tablets contain lactose.**
4. **you have kidney or liver disease, Parkinson's disease or fits (seizures).**
5. **you have problems with the heart and blood vessels.**
6. **you have, or have a history of blood clots.**
7. **you 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 Amipride 400.**
8. **you suffer from dementia.**
9. **you have 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.**
10. **you have risk factors for stroke.**
11. **you have a history, or family history, of breast cancer.**

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 AMIPRIDE 400, 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, clozapine, chlorpromazine, trifluoperazine, pimozide, haloperidol, imipramine and lithium
- diuretics
- stimulant laxatives
- glucocorticosteroids
- diagnostics drugs such as tetracosactides
- medicines taken for anxiety or to help you sleep
- anaesthetics (a 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

If you are unsure about any medicine you are taking, you should check with your doctor or pharmacist. They will have more information on medicines to be careful of while you are taking Amipride 400.

How to take AMIPRIDE 400**How much to take**

Your doctor will tell you how many tablets you need to take each day and when to take them. 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.

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

How to take it

Swallow the tablets with a glass of water. Tablets should preferably be taken before meals. Take your prescribed dose at about the same time each day.

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 the missed dose as soon as you remember, and then go back to taking your tablets as you would normally.

Do not take a double dose to make up for the dose you missed.

Ask your doctor or pharmacist if you are not sure what to do.

How long to take it for

It is important that you do NOT stop taking AMIPRIDE 400 unless your doctor tells you. Do not stop taking it, even if you feel better. It is very important to continue taking your medicine to help you stay well.

If you take too much (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 AMIPRIDE 400. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

If you take too much AMIPRIDE 400, you may feel drowsy or have slurred speech.

While you are taking it

Things you must do

It is very important to continue taking Amipride 400 because it will help you stay well.

Tell all doctors, dentists and pharmacists who are treating you that you are taking Amipride 400.

While you are taking Amipride 400, tell your doctor or pharmacist before you start any new medicine.

Make sure you use a contraceptive to prevent pregnancy during treatment with Amipride 400. If you become pregnant while 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 to be careful of

Amipride 400 may cause drowsiness in some people.

Be careful driving or operating machinery until you know how Amipride 400 affects you.

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.

The effects of alcohol could be made worse while taking Amipride 400. It is NOT recommended that you drink alcohol while taking Amipride 400.

Be careful while taking antihistamines, sleeping tablets or tablets to relieve pain while taking this medicine. Amipride 400 can increase drowsiness caused by medicines affecting your nervous system.

Things you must NOT do

Do not drive or operate machinery until you know how Amipride 400 affects you.

Do not give Amipride 400 to anyone else. Your doctor has prescribed it for you and your condition.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Amipride 400.

Like other medicines, amipride 400 can cause some side effects. If they occur, most are likely to be minor and temporary. However, some may be serious and may need medical attention. Some of the side effects are dose related, so it is important that you never exceed your prescribed dose.

While you are taking Amipride 400

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 Amipride 400.

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 Amipride 400 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 amipride 400 is lowered by your doctor or if your doctor prescribes you an additional medicine.

High blood sugar has been reported in patients taking Amipride 400. 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 more quickly than normal.

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

- muscle symptoms including pain, weakness, twitching or stiffness
- abnormal movements mainly of the face or tongue
- fever
- unexplained infections
- faster breathing
- sweating
- yellowing of the skin and eyes, also called jaundice
- light coloured bowel motions
- dark coloured urine

If this occurs, stop taking Amipride 400 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.

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

Tell your doctor if you notice any symptoms that worry you, even if you think the problems are not connected with the medicine or are not listed in this leaflet.

After using AMIPRIDE 400

Storage

Keep your medicine 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 a cool, dry place where the temperature stays below 25°C.

Do not store this, 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.

Disposal

If your doctor tells you to stop taking this medicine, 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

AMIPRIDE 400 is a white to off white 18 x 8 mm capsule shaped, film coated tablet with a break line on one side.

Each pack contains 60 tablets.

Ingredients

The active ingredient in AMIPRIDE 400 is amisulpride. Each AMIPRIDE 400 tablet contains 400 mg of amisulpride.

The tablets also contain:

- lactose monohydrate
- methylcellulose
- sodium starch glycolate
- magnesium stearate
- microcrystalline cellulose
- Eudragit E100
- purified talc
- macrogol 6000
- titanium dioxide.

This medicine contains sugars (as lactose).

This medicine does not contain gluten, sucrose, tartrazine or any other azo dyes.

Supplier

Arrow Pharma Pty Ltd
15 – 17 Chapel Street
Cremorne VIC 3121
Australian registration number:
AMIPRIDE 400 - AUST R 140231
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