

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.

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 AMIPRIDE 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 has been prescribed for you.

AMIPRIDE is available only with a doctor's prescription.

Before you take AMIPRIDE

When you must not take it

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

Signs of an allergic reaction may include skin rash, itching or hives, swelling of the face, lips or tongue wheezing or shortness of breath.

Do not take AMIPRIDE if you have:

- phaeochromocytoma, a rare tumour of the adrenal glands
- tumour of the pituitary gland
- breast cancer
- liver disease.

Do not take AMIPRIDE if you are breastfeeding.

AMIPRIDE passes into breast milk and may affect your baby.

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

Do not take AMIPRIDE if the packaging is torn or shows signs of tampering.

Do not give AMIPRIDE to children (under the age of puberty).

There is no specific information on the safety or efficacy of AMIPRIDE in pre-pubescent children.

Before you start to take it

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

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

Your doctor will discuss the risks and benefits of taking AMIPRIDE during pregnancy.

Tell your doctor if you plan to breastfeed.

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

- kidney problems
 - liver problems
 - Parkinson's disease
 - fits or seizures
 - heart or blood vessel problems.
- 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 AMIPRIDE.

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, or may affect how well it works. These include:

- other antipsychotics such as thioridazine, chlorpromazine, trifluoperazine, pimozide, haloperidol, imipramine and lithium
- medicines used to treat heart or blood pressure problems such as diltiazem, verapamil, clonidine, digoxin and beta-blockers
- intravenous amphotericin B (an anti-fungal-injection)
- diuretics (fluid tablets)
- stimulant laxatives
- glucocorticosteroids
- medicines to treat anxiety
- medicines to help you sleep
- medicines to treat depression
- some strong pain killers
- antihistamines, medicines to treat allergy.

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 AMIPRIDE.

How to take AMIPRIDE

How much to take

The dose varies from patient to patient.

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.

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

How to take AMIPRIDE

Swallow the tablets with a glass of water.

If you forget to take AMIPRIDE

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.

If you are not sure what to do, ask your doctor or pharmacist.

How long to take AMIPRIDE for

To properly control your condition, AMIPRIDE must be taken every day.

Keep taking AMIPRIDE for as long as your doctor recommends.

Do not stop taking AMIPRIDE, even if you feel better. It is very important to continue taking AMIPRIDE to help you stay well.

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

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

While you are taking AMIPRIDE

Things you must do

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

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

If you become pregnant while taking AMIPRIDE, tell your doctor.

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

Things you must not do

Do not stop taking AMIPRIDE, or lower the dose, without checking with your doctor.

Do not use AMIPRIDE to treat any other conditions unless your doctor tells you to.

Do not give AMIPRIDE 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 AMIPRIDE affects you.

AMIPRIDE may cause drowsiness, dizziness or lightheadedness. If any of these occur, do not drive, operate machinery or do anything else that could be dangerous.

If you are elderly or unwell, these effects may be increased.

Be careful when drinking alcohol while taking AMIPRIDE. It is not recommended that you drink alcohol while taking AMIPRIDE.

Side effects

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

Like all other medicines, AMIPRIDE 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.

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

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

- dizziness
- increased appetite, weight gain
- constipation
- dry mouth
- insomnia
- anxiety
- agitation.

These are the most common side effects of AMIPRIDE.

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 for a few days.

Sometimes trembling, noticeable muscle stiffness or spasm, slowness of movement, excess saliva or restlessness can occur, but this will usually be reduced if your dose of AMIPRIDE is lowered by your doctor or if your doctor prescribes you an additional medicine.

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

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

If this occurs, stop taking AMIPRIDE immediately and contact your doctor.

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

- breast pain
- milk secretion
- absence of the monthly period
- changes in the regularity of 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
- impotence.

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 AMIPRIDE

Storage

Keep AMIPRIDE 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 AMIPRIDE or any other medicine in the bathroom or near a sink.

Do not leave AMIPRIDE in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking AMIPRIDE, 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 is a white capsule shaped tablet marked "AM | 400.

Each pack contains 60 tablets.

Ingredients

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

The tablets also contain:

- lactose
- methylcellulose

- sodium starch glycollate
- magnesium stearate
- microcrystalline cellulose
- Eudragit E100
- purified talc
- macrogol 6000
- titanium dioxide.

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

Supplier

Sigma Pharmaceuticals (Australia) Pty Ltd
96 Merrindale Drive
Croydon Vic 3136
Tel: 03 - 9839 2800

Australian registration number:
AMIPRIDE 400 - AUST R 140231

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