

APO-Amisulpride

Contains the active ingredient: amisulpride

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

Read this leaflet carefully before taking your medicine.

This leaflet answers some common questions about amisulpride. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

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

What this medicine is used for

The name of your medicine is APO-Amisulpride. It contains the active ingredient amisulpride. It 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.

Ask your doctor if you have any questions about why this medicine has been prescribed for you. Your doctor may have prescribed this medicine for another reason.

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

There is no evidence that this medicine is addictive.

Use in children

This medicine must not be taken by children up to the age of puberty. There is limited information on the use of amisulpride in adolescents, therefore the use of amisulpride from puberty to the age of 18 years is not recommended.

Before you take this medicine

When you must not take it

Do not take this medicine if:

- You are taking any of the following medicines:
 - medicines used to treat irregular heart rhythm such as quinidine, disopyramide, amiodarone and sotalol
 - bepridil, a medicine used to treat angina
 - intravenous vincamine, a medicine used to increase blood flow to the brain
 - cisapride, a medicine used to treat stomach problems
 - halofantrine, a medicine used to treat

malaria

- antibiotics such as intravenous erythromycin, pentamidine and sparfloxacin
- levodopa, a medicine used in Parkinson's disease
- antipsychotics such as thioridazine and sultopride
- methadone, a medicine used to treat pain or addiction

- You have or have had any of the following medical conditions:
 - breast cancer
 - liver disease
 - tumour of the pituitary gland, a small gland at the base of the brain
 - pheochromocytoma, a rare tumour of the adrenal glands which sits near the kidneys
- You are breast-feeding or plan to breastfeed. Amisulpride may pass into human breast milk.

• You are hypersensitive to, or have had an allergic reaction to amisulpride or any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include: shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; itching or hives on the skin.

If you think you are having an allergic reaction, contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.

- The expiry date (EXP) printed on the pack has passed.
- The packaging is torn, shows signs of tampering or it does not look quite right.

Before you start to take it

Before you start taking this medicine, tell your doctor if:

1. You have allergies to:
 - any other medicines
 - any other substances, such as foods, preservatives or dyes.
2. You have or have had any medical conditions, especially the following:
 - kidney disease
 - liver disease
 - parkinson's disease or fits (seizures)
 - problems with the heart or blood vessels.
 - risk factors for stroke
 - history of blood clots.
 - a family history of, hyperglycaemia (high sugar levels in the blood).
Your doctor may recommend monitoring your blood sugar levels while you are taking amisulpride tablets.
 - suffer from dementia.
 - 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.
 - you have a history or family history of breast cancer
3. You are currently pregnant or you plan to become pregnant.

Do not take this medicine whilst pregnant until you and your doctor have discussed the risks and benefits involved.

Like most antipsychotic medicines, amisulpride is not recommended for use during pregnancy. There have been some reports of side effects such as shaking, muscle stiffness, breathing difficulty and problems feeding in newborn babies whose mothers have taken this type of medicine during the third trimester of pregnancy.

4. You suffer from lactose intolerance because APO-Amisulpride tablets contain lactose.
5. You are planning to have surgery.
6. You are currently receiving or are planning to receive dental treatment.
7. You are taking or are planning to take any other medicines.
This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

Taking other medicines

Some medicines may be affected by amisulpride or may affect how well it works. 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
- Other antipsychotics such as thioridazine, chlorpromazine, trifluperazine, pimozide, haloperidol, imipramine and lithium
- Diuretics
- Stimulant laxatives
- Glucocorticosteroids
- Diagnostics drugs such as tetracosactides
- Medicines taken for anxiety or to help you sleep
- 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 taking any of these medicines you may need a different dose or you may need to take different medicines.

Other medicines not listed above may also interact with amisulpride.

How to take this medicine

Follow carefully all directions given to you by your doctor or pharmacist. Their instructions may be different to the information in this leaflet.

How much to take

Your doctor or pharmacist will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines.

Do not stop taking your medicine or change your dosage without first checking with your doctor.

How to take it

The tablets should be swallowed whole with a glass of water.

When to take it

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

Doses should be taken preferably before meals.

How long to take it for

Continue taking your medicine for as long as your doctor tells you. It is important that you do NOT stop taking this medicine unless your doctor tells you. Do not stop taking this medicine just because you feel better.

Make sure you have enough to last over weekends and holidays.

If you forget to take it

If it is almost time to take your next dose, skip the missed dose and take your next dose at the usual time. 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 missed doses.

This may increase the chance of experiencing side effects.

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

If you take too much (overdose)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively go to the Accident and Emergency department at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are taking this medicine

Things you must do

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- you are pregnant or are planning to become pregnant
- you are breastfeeding or are planning to breastfeed
- you experience more unexplained infections or fever
- you are about to have any blood tests
- you are going to have surgery or are going into hospital.

Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

Things you must not do

Do not:

- Give this medicine to anyone else, even if their symptoms seem similar to yours
- Take your medicine to treat any other condition unless your doctor or pharmacist tells you to
- Stop taking your medicine suddenly, or change the dosage, without first checking with your doctor.

Things to be careful of

Be careful when driving or operating machinery until you know how this medicine affects you. This medicine may cause drowsiness in some people.

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 this medicine. It is NOT recommended that you drink alcohol while taking this medicine.

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

Tell your doctor immediately, or go to the nearest hospital, if you have suicidal thoughts, mental/mood changes or aggressive behaviour.

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.

Possible side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking amisulpride or if you have any questions or concerns.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not. Some of the side effects are dose related, so it is important that you do not take more than the prescribed dose.

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

This list includes the more common side effects.

Mostly, these are mild:

- drowsiness
- weight gain
- dizziness
- Increased appetite
- nausea
- vomiting
- constipation
- dry mouth
- insomnia
- anxiety
- agitation

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 this medicine for a few days.

Sometimes trembling, noticeable muscle stiffness or spasm, slowness of movement, excess saliva, restless, 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 this medicine is lowered by your doctor or if your doctor prescribes you an additional medicine.

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

- Breast pain
- Milk secretion
- An absence of their monthly period
- Change 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.

If you experience any of the following, stop taking your medicine and contact your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

You may need urgent medical attention or hospitalisation.

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

Other side effects not listed above may occur in some patients.

Allergic reactions

If you think you are having an allergic reaction to Amisulpride, tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- 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
- fainting
- hayfever-like symptoms

Storage and disposal

Storage

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 25°C.

Do not store your medicine, 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 this 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.

Disposal

If your doctor or pharmacist tells you to stop taking this medicine or they have passed their expiry date, your pharmacist can dispose of the remaining medicine safely.

Product description

What APO-Amisulpride looks like

Amisulpride 50 mg tablets - white to off-white 6.0mm, round, bi-convex tablets with breakline on one side.

Amisulpride 100 mg tablets - white to off-white 8.0mm, round, flat tablets with breakline on one side.

Amisulpride 200 mg tablets - white to off-white 11.0mm, round, flat tablets with breakline on one side.

Amisulpride 400 mg tablets - white to off-white, 18 x 8mm capsule shaped, film-coated tablets with breakline on one side.

*Not all strengths, pack types and/or pack sizes may be available.

Ingredients

Each tablet contains 50, 100, 200 or 400 mg of amisulpride as the active ingredient.

It also contains the following inactive ingredients:

- lactose
- methylcellulose
- sodium starch glycollate (type A)
- microcrystalline cellulose
- magnesium stearate

The 400 mg tablets only also contain:

- basic butylated methacrylate copolymer
- titanium dioxide
- talc
- macrogol 6000.

This medicine is gluten-free, sucrose-free, tartrazine-free and free of other azo dyes.

Australian Registration Numbers

APO-Amisulpride 50 mg tablet (blister pack of 60, 90,100): AUST R 178900.

APO-Amisulpride 100 mg tablet (blister pack of 30, 50, 60, 90, 100): AUST R 178904.

APO-Amisulpride 200 mg tablet (blister pack of 50, 60, 90, 100): AUST R 178902.

APO-Amisulpride 400 mg tablet (blister pack of 10 (sample), 50, 60,90, 100): AUST R 178898.

Sponsor

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