

# **APO-Amisulpride**

Amisulpride

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## **Consumer Medicine Information**

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

## **What is in this leaflet**

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.

All medicines have benefits and risks. Your doctor has weighed the risks of you using this medicine 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 your medicine.**

You may need to read it again.

## **What this medicine is used for**

Amisulpride belongs to a group of medicines called antipsychotics.

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.

This medicine is not addictive.

## **Before you take this medicine**

### **When you must not take it**

**Do not take this medicine if you have an allergy to:**

- amisulpride
- any of the ingredients listed at the end of this leaflet.

Some 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
- rash, itching or hives on the skin.

**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.

**Tell your doctor if 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
- phaeochromocytoma, a rare tumour of the adrenal glands which sits near the kidneys

**Tell your doctor if you are breast-feeding or plan to breastfeed.**

Amisulpride may pass into human breast milk, and therefore should not be taken when breastfeeding.

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

**Do not take this medicine if the expiry date printed on the pack has passed, 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 disease
- liver disease
- Parkinson's disease
- fits or seizures
- problems with the heart or blood vessels
- risk factors for stroke
- history of blood clots
- suffer from dementia
- a history or family history of breast cancer
- 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.

- 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.

**Tell your doctor if 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.

**Tell your doctor if you suffer from lactose intolerance.**

APO-Amisulpride tablets contain lactose.

**Tell your doctor if you are planning to have surgery, or you are currently receiving or are planning to receive dental treatment.**

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

## 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.**

Some medicines and amisulpride may interfere with each other. 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 (medicines 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 this medicine 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.

Other medicines not listed above may also interact with amisulpride.

## **How to take this medicine**

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

They may differ to 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 much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines.

## **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 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.

**Amisulpride should be taken preferably before meals.**

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

**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.

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

**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 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 missed doses.**

**This may increase the chance of experiencing side effects.**

**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 to help you remember.**

## **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 your nearest hospital, if you think that you or anyone else may have taken too much of this medicine. 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**

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

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

**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 suicidal thoughts, mental/mood changes or aggressive behaviour, including:**

- 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.

**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.

**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.

**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.

## **Things you must not do**

**Do not take this medicine 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.**

## **Things to be careful of**

**Be careful when driving or operating machinery until you know how this medicine affects you.**

This medicine may cause dizziness or drowsiness in some people 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 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.

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

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.**

**Amisulpride 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 amisulpride.**

This medicine helps most people with schizophrenia, but it may have unwanted side effects in a few 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 lists 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, dizziness
- weight gain, increased appetite
- nausea, vomiting
- constipation
- dry mouth
- blurred vision
- insomnia
- anxiety, agitation
- problems with orgasm

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 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.

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

**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, contact your doctor immediately or go to Accident and Emergency at your nearest hospital:**

- allergic reaction, including symptoms such as 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
- muscle twitching
- abnormal movements, mainly of the face or tongue
- fever, unexplained infections
- faster breathing
- sweating
- muscle stiffness.

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 occur in some patients.

## **Storage and Presentation**

### **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 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 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.**

## **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:

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

The 400 mg tablets also contain:

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

This medicine is free from gluten, sucrose, tartrazine and 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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