

Package leaflet: Information for the user

Amisulpride 50mg, 100mg, 200mg & 400mg Tablets

amisulpride

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

What is in this leaflet

1. What Amisulpride Tablets are and what they are used for
2. What you need to know before you take Amisulpride Tablets
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1. What Amisulpride Tablets are and what they are used for

Amisulpride belongs to a group of medicines called 'antipsychotics'. The tablets are used to treat an illness called schizophrenia.

Schizophrenia can make you feel, see or hear things which do not exist, have strange and frightening thoughts, change how you act, and make you feel alone. Sometimes people with these symptoms may also feel tense, anxious or depressed. Amisulpride tablets work by improving disturbed thoughts, feelings and behaviour. It is used to treat schizophrenia when it starts and also over the long term.

2. What you need to know before you take Amisulpride Tablets

Do not take Amisulpride Tablets:

- If you are allergic (hypersensitive) to amisulpride or any of the other ingredients of this medicine (listed in section 6). Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- If you are pregnant or might become pregnant (see 'Pregnancy and breast-feeding' section).
- If you have breast cancer or something called 'a prolactin dependent tumour'.
- If you have a tumour on the adrenal gland (called pheochromocytoma).
- If you are taking other medicines which could change your heart rate such as medicines which are used to control your heart beat (see 'Taking other medicines' section).
- If you are taking levodopa, a medicine to treat Parkinson's disease (see 'Taking other medicines' section).
- If you have a pituitary tumour.
- If the patient is under 15 years old. Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Amisulpride Tablets.

Warnings and precautions

Talk to your doctor or pharmacist before taking Amisulpride Tablets.

- If you have kidney problems.
- If you have Parkinson's disease.
- If you have ever had fits (epileptic seizures).
- If you have an unusual heart rate (rhythm)
- If you have a slow heart beat (less than 55 beats per minute)
- If you have low potassium levels in your blood
- If you or someone else in your family has a history of blood clots, as medicines like these have been associated with formation of blood clots
- If you have a heart disease or family history of heart problems
- If your doctor have told you that you might have a stroke
- If you are diabetic or have been told you have an increased risk of having diabetes
- If you are elderly. This is because elderly people are more likely to get low blood pressure or feel sleepy.
- If you are elderly and have dementia
- If you have a history or a family history of breast cancer.
- If you have high levels of prolactin, a hormone produced in the pituitary gland

Severe liver problems have been reported with Amisulpride Tablets. Talk to your doctor immediately if you experience fatigue, loss of appetite, nausea, vomiting, abdominal pain or yellow discoloration of the eyes or skin.

During treatment, if you develop muscle stiffness or muscle loss associated with muscle pain (rhabdomyolysis), faster breathing, sweating, impaired consciousness (drowsiness/sleepiness) and unexplained fever: stop your treatment immediately and consult your doctor urgently as these symptoms are signs of a rare syndrome called neuroleptic malignant syndrome which can have a potential fatal outcome (see section 4).

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Amisulpride Tablets.

Other medicines and Amisulpride Tablets

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines you buy without a prescription, including herbal medicines. This is because Amisulpride Tablets can affect the way some other medicines work.

Also some medicines can affect the way Amisulpride Tablets works.

In particular, do not take this medicine and tell your doctor if you are taking any of the following medicines:

- Medicines used to control your heart beat such as quinidine, disopyramide, procainamide, amiodarone and sotalol
- Bepridil, used to treat heart disease
- Cisapride, used to treat heartburn
- Thioridazine or sultopride, used to treat mental illness
- Methadone, used to treat pain and opiate addiction
- Antibiotics such as erythromycin (given by injection) or sparfloxacin
- Vincamine (given by injection), used for brain circulation problems
- Halofantrine, used for malaria
- Pentamidine used for pneumonia
- Levodopa, a medicine to treat parkinson's disease
- Clozapine, used to treat schizophrenia

Tell your doctor if you are taking any of the following medicines:

- medicines for depression or to calm emotional and mental illness such as pimozone, haloperidol, imipramine, and lithium
- medicines for high blood pressure and migraine such as clonidine, diltiazem, verapamil, guanfacine or digitalis
- medicines which may lower potassium levels. This includes water tablets such as bendrofluzide or hydrochlorothiazide, some laxatives, glucocorticoids (used to treat severe asthma and other inflammatory disorders), tetracosactides and amphotericin (used to treat fungal infections)
- medicines for severe pain called opiates such as morphine and pethidine
- pain-killers such as tramadol and indomethacin
- medicines to help you sleep such as barbiturates and benzodiazepines
- anaesthetics
- antihistamines such as promethazine which make you sleepy

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Amisulpride.

Amisulpride Tablets with food and drink

- Swallow Amisulpride Tablets with plenty of water before a meal
- Do not drink alcohol while you are taking Amisulpride Tablets. This is because it can affect the way the medicine works.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Pregnancy

Amisulpride Tablets are not recommended during pregnancy and in women of childbearing potential not using effective contraception. If you use Amisulpride Tablets during the last three months of pregnancy, your baby may suffer from agitation, increased muscle tension, involuntary trembling of the body, sleepiness, breathing problems, or difficulty in feeding. Talk to your doctor, if your baby develops any of these symptoms.

Breast-feeding

You should not breast-feed during therapy with Amisulpride Tablets. Talk to your doctor about the best way to feed your baby if you are taking Amisulpride Tablets.

Driving and using machines

You may feel less alert, drowsy or sleepy and have blurred vision while taking this medicine. If this happens, do not drive or use any tools or machines.

Amisulpride Tablets contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Amisulpride Tablets

Always take this medicine exactly how your doctor or pharmacist has told you to. Check with your doctor or pharmacist if you are not sure.

Taking this medicine

- Take this medicine by mouth
- Swallow the tablets whole with a drink of water. Do not chew your tablets.
- Take before a meal.
- If you feel the effect of your medicine is too weak or too strong, do not change the dose yourself, but ask your doctor.

How much to take

The amount of Amisulpride Tablets you take will depend on your illness. Follow your doctor's instructions carefully.

Adults

- The usual dose is between 50mg and 800mg each day.
- Your doctor may start you on a lower dose if necessary.
- Doses up to 400mg each day can be taken as a single dose. Take the dose at the same time each day.
- Doses above 400mg should be taken as half in the morning and half in the evening.

Elderly

- Your doctor will need to keep a close check on you as you are more likely to have low blood pressure or sleepiness due to this medicine

People with kidney problems

- Your doctor may need to give you a lower dose

Children under 15 years of age

Amisulpride Tablets should not be given to children under 15 years of age

If you take more Amisulpride Tablets than you should

If you take more tablets than you should, tell a doctor or go to a hospital casualty department straight away. Take the medicine pack with you. This is so the doctor knows what you have taken. The following effects may happen: feeling restless or shaky, rigid muscles, feeling drowsy or sleepy which could lead to a loss of consciousness.

If you forget to take Amisulpride Tablets

If you forget to take a dose, take it as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose. Do not take a double dose to make up for a forgotten dose.

If you stop taking Amisulpride Tablets

Keep taking Amisulpride Tablets until doctor tells you to stop. Do not stop taking Amisulpride Tablets if you feel better. If you stop, your illness may get worse or come back.

Unless your doctor tells you otherwise, Amisulpride tablets should not be stopped suddenly. Stopping treatment suddenly may cause withdrawal effects such as:

- feeling or being sick
- sweating
- difficulty sleeping or feeling very restless
- muscle stiffness or unusual body movements
- your original condition may come back

Blood tests

Taking Amisulpride Tablets may affect the results of some blood tests. These include tests to measure the hormone called 'prolactin' and liver tests. If you are going to have a blood test, it is important to tell your doctor you are taking Amisulpride Tablets. If you have any further questions on the use of this medicine ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Amisulpride Tablets can cause side effects, although not everybody gets them.

Stop taking Amisulpride Tablets and see a doctor or go to a hospital straight away if:

- You have a high temperature, sweating, stiff muscles, fast heartbeat, fast breathing and feel confused, drowsy or agitated. These could be the symptoms of a serious but rare side effect called 'neuroleptic malignant syndrome', which is a potentially fatal complication.
- You have an unusual heart rate, very fast heart rate or chest pain which could result in a heart attack or life-threatening heart disorder
- You have pain or swelling in your leg, chest pain or difficulty breathing. These could be symptoms of a blood clot

Uncommon (may affect up to 1 in 100 people):

- You have an allergic reaction. The signs may include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
- You have a fit (seizure)

Rare (may affect up to 1 in 1000 people):

- You get more infections than usual. This could be because of a blood disorder (agranulocytosis) or a decrease in the number of white blood cells (neutropenia)
- You have frequent infections such as fever, severe chills, sore throat or mouth ulcers. These could be signs of a blood problem called 'leukopenia'

Tell your doctor as soon as possible if you have any of the following side effects: Very common (may affect more than 1 in 10 people):

- Trembling, muscle stiffness or spasm, slow movement, producing more saliva than usual or feeling restless.

Common (may affect up to 1 in 10 people):

- Movements that you cannot control, mainly of the arms and legs (These symptoms can be reduced if your doctor lowers your dose of Amisulpride Tablets or prescribes an additional medicine)

Uncommon (may affect up to 1 in 100 people):

- Movements that you cannot control, mainly of the face or tongue

Other side effects include:

Common (may affect up to 1 in 10 people):

- Difficulty sleeping (insomnia) or feeling anxious or agitated
- Feeling drowsy or sleepy
- Constipation, feeling or being sick, dry mouth
- Putting on weight
- Unusual production of breast milk in women and men, breast pain
- Menstrual period stops
- Breast enlargement in men
- Difficulty in getting or maintaining an erection, or in ejaculating
- Feeling dizzy (which can be due to low blood pressure)

Uncommon (may affect up to 1 in 100 people):

- Slowing of the heart beat
- High blood sugar (hyperglycaemia)
- Increase in blood pressure
- Difficulty in passing water (urine)
- Confusion

- Nasal congestion
- Problems with your liver
- Osteopaenia (low bone mineral density)
- Osteoporosis. This is when your bones are more likely to break
- You develop a lung infection after inhaling food, liquid, saliva or nasal secretions (aspiration pneumonia)
- Blood disorders such as Hypertriglyceridemia (high levels of triglycerides in your blood) and Hypercholesterolemia (high levels of cholesterol in your blood)

Rare (may affect up to 1 in 1000 people):

- Urticaria (hives)
- Swelling beneath the skin (angioedema)
- Hyponatraemia (low sodium levels in your blood)
- Feeling unwell, confused or weak, feeling sick (nausea), loss of appetite, feeling irritable. This could be signs of an illness called syndrome of inappropriate antidiuretic hormone secretion (SIADH)
- Benign (non-cancerous) pituitary tumour such as prolactinoma

Not known (frequency cannot be estimated from the available data)

- Restless legs syndrome (uncomfortable feeling in legs temporarily relieved by movement and symptoms getting worse at the end of the day)
- Liver tissue damage
- Increased sensitivity of your skin to sun and ultraviolet light
- Falls due to reduced body balance, sometimes leading to fractures
- Rhabdomyolysis (breakdown of muscles associated with muscle pain)
- Elevated levels of creatine phosphokinase (blood test indicating muscle damage)

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Amisulpride Tablets

Keep this medicine out of the sight and reach of children.

- Do not store above 25°C
- Store in the original package.
- Do not use after the expiry date on the carton, the expiry date refers to the last day of the month.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Amisulpride Tablets contain:

The **active** ingredient is amisulpride. Each 50mg tablet contains 50mg of amisulpride. Each 100mg tablet contains 100mg of amisulpride. Each 200mg tablet contains 200mg of amisulpride. Each 400mg tablet contains 400mg of amisulpride.

The other substances for Amisulpride 50mg, 100mg & 200mg Tablets are maize starch, lactose monohydrate, methylcellulose 400cps, colloidal anhydrous silica and magnesium stearate.

The other substances in Amisulpride 400mg Tablets are lactose monohydrate, sodium starch glycollate, magnesium stearate, microcrystalline cellulose, methylcellulose 400cps, basic butylated methacrylate copolymer, titanium dioxide (E171), talc and macrogol 6000.

What Amisulpride Tablets look like and contents of the pack

Amisulpride 50mg, 100mg & 200mg Tablets
White to off-white, round, scored, uncoated tablets with 50, MAM100 and MAM200 marked on one side respectively.

Amisulpride 400mg Tablets

White to off-white, ovoidal shaped, biconvex, scored, film coated tablets marked MAM400 on one side.
Amisulpride 50mg, 100mg, 200mg & 400mg Tablets are available in blister packs of 60 tablets.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
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