



Amisulpride 50 mg tablets Amisulpride 100 mg tablets Amisulpride 200 mg tablets Amisulpride 400 mg tablets amisulpride

(Referred to as Amisulpride tablets throughout this leaflet)

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. See section 4.

What is in this leaflet

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1. What Amisulpride tablets are and what they are used for

Amisulpride tablets contain a medicine called amisulpride. This belongs to a group of medicines called ‘anti-psychotics’. It is 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 works 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 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 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 levodopa, a medicine used to treat Parkinson’s disease (see ‘Taking other medicines’ section)
- if you have been diagnosed with a pituitary tumour
- if you are 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
- You have Parkinson’s disease
- You have ever had fits (convulsions or epileptic seizures)
- You have an unusual heart rate (rhythm)
- You have heart disease or family history of heart problems
- Your doctor has told you that you might have a stroke
- 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.
- You are diabetic or have been told you have an increased risk of having diabetes
- You have a slow heart beat (less than 55 beats per minute)
- You have been told you have a low amount of potassium in your blood.
- You are elderly. This is because elderly people would be more likely to get low blood pressure or feel sleepy
- You are elderly and have dementia
- You have a low number of white blood cells (agranulocytosis). This means you may get infections more easily than usual.
- You or someone else in your family has a history of breast cancer
- You have high levels of prolactin, a hormone produced by the pituitary gland

Severe liver problems have been reported with amisulpride. Talk to your doctor immediately if you experience fatigue, loss of appetite, nausea, vomiting, abdominal pain or yellow discolouration 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 potentially 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

Tell your doctor if you are taking, have recently taken or might take 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 work.

In particular, do not take this medicine, and tell your doctor if you are taking:

- Levodopa, a medicine to treat Parkinson’s disease

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

- Medicines used to control your heart beat such as quinidine, disopyramide, amiodarone and sotalol
- Clozapine, used to treat schizophrenia
- Other anti-psychotic medicines used for mental problems.
- Medicines for severe pain called opiates such as morphine or pethidine
- Medicines for high blood pressure and heart problems such as, diltiazem, verapamil, guanfacine and digitalis
- Clonidine used for migraines, flushing or high blood pressure.
- Mefloquine used to treat malaria.
- Medicines which help you sleep such as barbiturates and benzodiazepines
- Painkillers such as tramadol and indometacin
- Anaesthetics
- Antihistamines such as promethazine which make you sleepy
- Drugs called ‘dopamine agonists’ such as ropinirole and bromocriptine

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

Amisulpride tablets with food, drink and alcohol

- 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 and breast-feeding

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 contain 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.

Amisulpride tablets contain sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially ‘sodium- free’.

3. How to take Amisulpride tablets

Always take this medicine exactly as described in this leaflet or as your doctor has told you. Check with your doctor if you are not sure.

The recommended dose you take will depend on your illness. Follow your doctor’s instructions carefully.

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.

Adults

- The usual dose is between 50 mg and 800 mg amisulpride each day.
- Your doctor may start you on a lower dose if necessary.
- If necessary, your doctor can prescribe up to 1200 mg each day.
- Doses up to 400 mg each day can be taken as a single dose. Take the dose at the same time each day.
- Doses above 400 mg should be taken as half of the dose 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 a dose, take it as soon as you remember it. 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 your doctor tells you to stop. Do not stop taking Amisulpride tablets just because 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 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, this medicine 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:

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

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

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

- 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 a very fast or unusual heart rate, or chest pain which could result in a heart attack or life-threatening heart disorder
- You have blood clots in the veins especially in the legs (symptoms include swelling, pain and redness in the leg), which may travel through blood vessels to the lungs causing chest pain and difficulty in breathing. If you notice any of these symptoms seek medical advice immediately.

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 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)
- Blurred vision

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

- Slowing of the heart beat
- High blood sugar (hyperglycaemia)
- Feeling confused

- Nasal congestion
- A condition called ‘osteoporosis’. This is when your bones are more likely to break
- Osteopenia (low bone mineral density)
- High levels of fat (triglycerides) or cholesterol in the blood
- Lung infection after accidental inhalation of food or liquid, with risk of pneumonia
- Increase in blood pressure
- Difficulty passing water (urine)
- Liver tissue damage

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

- Non-cancerous benign pituitary tumour (such as prolactinoma)
- Feeling unwell, confused or weak, feeling sick (nausea), loss of appetite, feeling irritable. This could be an illness called a syndrome of inappropriate antidiuretic hormone secretion (SIADH)
- Tired, weak, confused, have muscles that ache, are stiff or do not work well. This may be due to low sodium levels in your blood

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

- Restless legs syndrome (uncomfortable feeling in legs temporarily relieved by movement and symptoms getting worse at the end of the day)
- 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)
- Increased level of creatinine phosphokinase (blood test indicating muscle damage)

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: 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 use this medicine after the expiry date which is stated on the carton and blister foil. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6.Contents of the pack and other information

What Amisulpride tablets contain

The active substance is amisulpride. Each tablet contains 50mg, 100mg, 200mg or 400mg of amisulpride. The other ingredients are sodium starch glycolate, lactose monohydrate, microcrystalline cellulose, hypromellose and magnesium stearate.

What Amisulpride tablets look like and contents of the pack

- Amisulpride 50mg tablets are white, round, flat tablets, with diameter 7 mm.
- Amisulpride 100mg tablets are white, round, flat tablets, with diameter 9.5 mm and embossed MC on one side.
- Amisulpride 200mg tablets are white, round, flat tablets, with diameter 11.5 mm and scored on one side. The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.
- Amisulpride 400mg tablets are white, biconvex, capsule-shaped tablets, with dimensions 19 x 10 mm and scored on both sides. The score lines are only to facilitate breaking for ease of swallowing and not to divide into equal doses.

Amisulpride 50 mg tablets are supplied in PVC/PVDC-Alu blisters in packs containing 12, 30, 60, 90 or 100 tablets. Amisulpride 100 mg, 200 mg and 400 mg tablets are supplied in PVC/PVDC-Alu blisters in packs containing 30, 60, 90 or 100 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
DHP Healthcare Ltd
13 Hanover Square, London W1S 1HN, United Kingdom

Manufacturer
Medochemie Ltd
Factory AZ, 2 Michail Irakleous street, Agios Athanasios Industrial Area, 4101 Limassol, Cyprus

Other Formats

To request a copy of this leaflet in Braille, large print or audio please call 0330 1359 454

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