

PACKAGE LEAFLET: INFORMATION FOR THE USER

Amisulpride 100mg/ml Oral Solution
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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

In this leaflet:

1. What Amisulpride Oral Solution is and what it is used for
2. What you need to know before you take Amisulpride Oral Solution
3. How to take Amisulpride Oral Solution
4. Possible side effects
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1. What Amisulpride Oral Solution is and what it is used for
Your medicine is called Amisulpride 100mg/ml Oral Solution (called Amisulpride Oral Solution throughout this leaflet). 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 Oral Solution 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 Oral Solution

Do not take Amisulpride Oral Solution

- if you are allergic (hypersensitive) to amisulpride or any of the other ingredients of Amisulpride Oral Solution (listed in section 6 below); 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, bromocriptine used in pituitary problems and ropinirole used in restless leg syndrome. (See 'Taking other medicines' section)
 - if you have been diagnosed with a pituitary tumour
 - if you are under 18 years of age.
- 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 Oral Solution.

Warnings and precautions:

Talk to your doctor, pharmacist or nurse before taking Amisulpride Oral Solution if:

- You have kidney problems
- You have ever had fits (epileptic seizures).
- You have Parkinson's disease
- You have heart disease, or a family history of heart problems
- You have had a stroke or your doctor has told 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 a 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 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. A small increase in the number of deaths of elderly people with dementia has been reported for patients taking antipsychotics compared to those not receiving antipsychotics
- You have an unusual heart rate (rhythm)
- You have a low number of white blood cells (agranulocytosis). This means you may get infections more easily than usual
- You have frequent infections such as fever, severe chills, sore throat or mouth ulcers. These could be signs of a blood problem called 'leukopenia'
- You or someone else in your family has a history of breast cancer
- You have high levels of prolactin.

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

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

Other medicines and Amisulpride Oral Solution

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 Oral Solution can affect the way some other medicines work. Also some medicines can affect the way Amisulpride Oral Solution works.

Do not take Amisulpride Oral Solution.

Please also tell your doctor or pharmacist if you are taking any of the following medicines: following medicines:

- Levodopa, a medicine to treat Parkinson's disease
- Drugs called 'dopamine agonists' such as ropinirole and bromocriptine.

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
- Mefloquine used to treat malaria
- Medicines for high blood pressure and heart problems such as diltiazem, verapamil, guanfacine or digitalis
- Clonidine used for migraines, flushing or high blood pressure
- Medicines which help you sleep such as barbiturates and benzodiazepines
- Pain-killers such as tramadol or indomethacin
- Anaesthetics. Inform your doctor or dentist that you are taking Amisulpride Oral Solution before you have an anaesthetic
- 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 Oral Solution.

Amisulpride Oral Solution with food, drink and alcohol

- A carbohydrate rich (starchy/sugary) meal may adversely affect how this medicine works. Therefore you should take Amisulpride Oral Solution before a meal and at about the same time(s) each day
- Take the solution with a drink that does not contain alcohol.
- Do not drink alcohol while you are taking Amisulpride Oral Solution. 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 Oral Solution is not recommended during pregnancy and in women of childbearing potential not using effective contraception.

If you use Amisulpride Oral Solution 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 Oral Solution. Talk to your doctor about the best way to feed your baby if you are taking Amisulpride Oral Solution.

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 Oral Solution contains parahydroxybenzoates (E216 propyl parahydroxybenzoate and E218 methyl parahydroxybenzoate). These may cause allergic reactions (possibly delayed).

This medicinal product contains 0.18mmol (4.02mg) sodium (salt) per 1ml of oral solution. To be taken into consideration by patients on a controlled sodium (salt) diet.

This medicinal product also contains small amounts of ethanol (alcohol), less than 0.5mg per 1ml of oral solution.



3. How to take Amisulpride Oral Solution

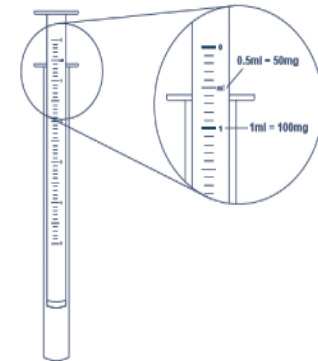
Always take Amisulpride Oral Solution exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

- Take this medicine by mouth
- Take the solution with a drink that does not contain alcohol.
- Use the graduated syringe to measure your medicine. Each 1ml of solution contains 100mg of your medicine
- 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.

A 5ml graduated syringe is provided with your medicine. Use the syringe to withdraw, from the bottle, the amount of Amisulpride Oral Solution that has been prescribed for you by your doctor.

Each 1ml of solution contains 100mg of your medicine. Each 0.5ml of solution contains 50mg of your medicine (see Figure A).

Figure A



The conversion of milligrams (mg) to millilitres (ml) is provided in the table below:

Amount of solution (ml)	Amount of medicine (mg)
0.5	50
1	100
2	200
3	300
4	400
5	500

The recommended dose is:

Use in children and adolescents

Adults

- The usual dose is between 0.5ml (50mg amisulpride) and 8ml (800mg amisulpride) each day
- Your doctor may start you on a lower dose if necessary
- If necessary your doctor can prescribe up to 1200mg (12ml) each day
- Doses up to 300mg (3ml) each day can be taken as a single dose
- Take the dose at the same time each day
- Doses above 300mg (3ml) 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.

Patients with kidney problems

Your doctor may need to give you a lower dose.

Use in children and adolescents

Amisulpride Oral Solution should not be given to children under 18 years of age.

If you take more Amisulpride Oral Solution than you should

If you take more solution 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 Oral Solution

If you forget to take 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 double the amount to make up for a forgotten dose.

If you stop taking Amisulpride Oral solution

- Keep taking Amisulpride Oral Solution until your doctor tells you to stop. Do not stop taking Amisulpride Oral Solution just because you feel better. If you stop, your illness may get worse or come back. Unless your doctor tells you otherwise, Amisulpride Oral Solution should not be stopped suddenly. Stopping treatment suddenly can lead to 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



4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop taking Amisulpride Oral Solution 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'
- 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 Oral Solution 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
- High levels of fat (triglycerides) or cholesterol in the blood
- Accidental inhalation of food with risk of pneumonia (lung infection)
- Increase in blood pressure
- Difficulty passing water (urine)
- Liver tissue damage.

Rare (may affect up to 1 in 1000 people)

- Noncancerous benign 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 still 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.

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 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 Oral Solution

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

Do not use after the expiry date stated on the carton and the bottle label after EXP. The expiry date refers to the last day of that month.

The medicinal product does not require any special storage conditions.

Once opened, use within 2 months.

Do not use this medicine if you notice any visible signs of damage to the bottle or deterioration in your medicine. Return it to your

pharmacist.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines that have passed the expiry date or have been open for more than 2 months. These measures will help to protect the environment.



6. Contents of the pack and other information

What Amisulpride Oral solution contains

- The active substance is amisulpride. Each 1ml of oral solution contains 100mg amisulpride
- The other ingredients are saccharin sodium, sodium gluconate, gluconolactone, hydrochloric acid (used to adjust the pH), methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), potassium sorbate, Toffee Flavour A (containing glycerol (E422) and ethanol) and purified water (see section 2, Before you take Amisulpride Oral Solution).

What Amisulpride Oral Solution looks like and contents of the pack

Amisulpride Oral Solution is a colourless to brown yellowish clear solution. It is available in an amber glass bottle containing 60ml of medicine. The pack also contains a 5ml, plastic oral dosing syringe.

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For information in large print, audio CD or Braille please telephone 00 44 (0)1283 495 280 or email medinfo@focuspharma.co.uk.

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