

Amisulpride 100mg/ml Sugar Free 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.

The name of your medicine is Amisulpride 100mg/ml Sugar Free Oral Solution but it will be referred to as 'Amisulpride' throughout this leaflet.

What is in this leaflet:

1. What Amisulpride is and what it is used for
2. What you need to know before you take Amisulpride
3. How to take Amisulpride
4. Possible side effects
5. How to store Amisulpride
6. Contents of the pack and other information

1. What Amisulpride is and what it is used for

Amisulpride 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

Do not take Amisulpride 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
- ▶ You are pregnant or might become pregnant (see 'Pregnancy and breast-feeding section')
- ▶ You have breast cancer or something called 'a prolactin dependent tumour'
- ▶ You have a pituitary tumour
- ▶ You have a tumour on the adrenal gland (called phaeochromocytoma)
- ▶ 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)
- ▶ You are taking levodopa, a medicine to treat Parkinson's disease (see 'Taking other medicines' section)
- ▶ 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.

Warning and precautions

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 potential fatal outcome (see section 4).

Take special care with Amisulpride

Check with your doctor or pharmacist before taking your medicine if:

- ▶ You have kidney problems
- ▶ You have Parkinson's disease
- ▶ You have ever had fits (epileptic seizures)
- ▶ You have a history or a family history of breast cancer
- ▶ You have high levels of prolactin, a hormone produced in the pituitary gland
- ▶ 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 are diabetic or have been told you have an increased risk of having diabetes
- ▶ 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
- ▶ Your doctor has told you that you have an increased risk of a blood clot
- ▶ 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.

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

Taking other medicines

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 can affect the way some other medicines work. Also some medicines can affect the way amisulpride 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 pimozide, haloperidol, imipramine, and lithium
- ▶ Medicines for severe pain called opiates such as morphine or pethidine
- ▶ Medicines for high blood pressure and migraine such as clonidine, diltiazem and verapamil, guanfacine and digitalis
- ▶ Medicines which may lower potassium levels. This includes water tablets such as bendro fluzide or hydrochlorothiazide, some laxatives, glucocorticoids (used to treat severe asthma and other inflammatory disorders), tetracosactides and amphotericin (used to treat fungal infections)
- ▶ Medicines which help you sleep such as barbiturates and benzodiazepines
- ▶ Pain-killers such as tramadol and indometacin
- ▶ 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.

Taking amisulpride with food and drink

- ▶ Take amisulpride with plenty of water before a meal
- ▶ Do not drink alcohol while you are taking amisulpride. 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 is not recommended during pregnancy and in women of childbearing potential not using effective contraception. If you use amisulpride 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. Talk to your doctor about the best way to feed your baby if you are taking amisulpride.

Driving and using machines

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

Amisulpride contains:

Methyl parahydroxybenzoate (E218): May cause allergic reactions (possibly delayed).

3. How to take Amisulpride

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

How much to take

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

Adults

- ▶ The recommended usual dose is between 0.5ml (50mg) and 8ml (800mg) each day
- ▶ Your doctor may start you on a lower dose if necessary
- ▶ If necessary your doctor can prescribe up to maximum of 12ml (1200mg) each day
- ▶ Doses up to 4ml (400mg) each day can be taken as a single dose. Take the dose at the same time each day
- ▶ Doses above 4ml (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 should not be given to children under 15 years of age.
- ▶ The use of this medicine is not recommended between 15 and 18 years old.

Route and method of administration

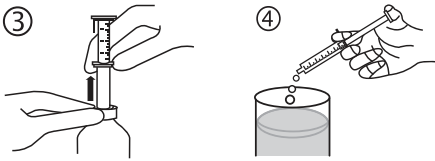
- ▶ Do not stop treatment yourself
- ▶ This medicinal product must be taken orally
- ▶ Take the solution with a drink that does not contain alcohol
- ▶ Use the measuring syringe provided in the pack to deliver the required dose as prescribed by your doctor. Each 1ml solution contains 100mg of your medicine
- ▶ If you feel the effect of your medicine is too weak or too strong, do not change the dose yourself, but ask your doctor.

Instructions for the use of syringe:

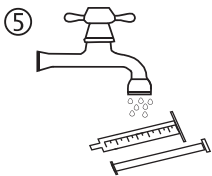
- a) Open the bottle: press the cap and turn it anticlockwise (Figure 1).
- b) Insert the syringe into the bottle and pull the piston upward to the graduation mark corresponding to the quantity in millilitres (ml) prescribed by your doctor (Figure 2).



- c) Remove the syringe from the bottle (Figure 3). Empty the syringe into any non-alcoholic drink by pushing the piston to the bottom of the syringe and drink it immediately (Figure 4).



- d) Wash the syringe with water and store in a clean place (Figure 5).



If you take more Amisulpride than you should

If you take more Amisulpride 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, low blood pressure, feeling drowsy or sleepy which could lead to a loss of consciousness or you may go into a coma.

If you forget to take Amisulpride

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. Keep taking amisulpride until your doctor tells you to stop. Do not stop taking amisulpride just because you feel better. If you stop, your illness may get worse or come back. Unless your doctor tells you otherwise, amisulpride 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.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

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

Stop taking Amisulpride 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 (agranulo cytosis) 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 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 Website 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

- ▶ 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 label after ‘EXP’. The expiry date refers to the last day of that month.
- ▶ This medicinal product does not require any special storage condition.
- ▶ Discard 60 days after first opening.
- ▶ 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 to protect the environment.

6. Contents of the pack and other information

What Amisulpride contains:

The active substance is amisulpride.

Each 1ml of oral solution contains 100mg of amisulpride.

The other ingredients are saccharin sodium, sodium gluconate, glucono-delta-lactone, hydrochloric acid concentrated, methyl parahydroxybenzoate (E218), caramel flavour (containing propylene glycol (E1520)) and purified water.

What Amisulpride looks like and contents of the pack:

Amisulpride oral solution is a clear, pale yellow colour solution with caramel odour, supplied in an amber glass bottle, with a child resistant, tamper evident plastic cap with a 5ml oral syringe with 0.5ml graduation for measuring and administering the dose.

Amisulpride oral solution is supplied in bottles containing 60 ml oral solution.

Marketing Authorisation Holder and Manufacturer:

SyriMed,
Unit 4, Bradfield Road,
Ruislip, Middlesex,
HA4 0NU, UK.

If this leaflet is hard to see or read, please call +44 (0) 208 515 3700 for help.

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