

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

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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.

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 have a 'prolactin dependent tumour', for example breast cancer or a pituitary gland tumour
- ▶ you have a tumour on the adrenal gland (called phaeochromocytoma) which releases hormones that cause high blood pressure
- ▶ the patient is under 15 years old.
- ▶ you are taking another medicine, when combined with Amisulpride is contraindicated (see 'Other medicines and Amisulpride').

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

Talk to your doctor or pharmacist before taking Amisulpride. Your doctor may do an ECG before giving you this treatment. This medicine can cause heart rhythm disturbances (see section 4). During treatment, if you experience muscle stiffness and impaired consciousness, accompanied by an unexplained fever: stop your treatment and consult your doctor immediately.

Use this medication with caution in the following cases if:

- ▶ you are elderly, especially with dementia, because of the risk of low blood pressure and sleepiness; the dose may be reduced by your doctor in case of kidney failure
- ▶ you have risk factors for stroke which occurs when the blood flow is suddenly interrupted in part of the brain
- ▶ you have kidney disease (kidney failure). Your doctor may reduce your dose
- ▶ you have Parkinson's disease
- ▶ you have ever had fits (epileptic seizures)
- ▶ 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 history of hyperprolactinemia (excessive prolactin in the blood) or a 'prolactin dependent tumour' for example, breast cancer or a pituitary tumour. In this case, your doctor should monitor you closely during treatment
- ▶ 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 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
- ▶ severe liver problems have been reported with Amisulpride. Tell your doctor immediately if you experience fatigue, loss of appetite, nausea, vomiting, abdominal pain, or yellow colour in your eyes or skin
- ▶ you have an infection or an unexplained fever occurs, your doctor may ask you to have a blood test. This medicine can cause a reduction in the number of white blood cells (see section 4. "Possible side effects").

Children and adolescents

- ▶ 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.

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

Other medicines and Amisulpride

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:

- ▶ drugs called 'dopamine agonists' other than to treat Parkinson's disease such as cabergoline, quinagolide
- ▶ drugs to treat anxiety or depression such as citalopram or escitalopram
- ▶ domperidone used to treat nausea and vomiting
- ▶ hydroxyzine used to treat anxiety or hives
- ▶ piperazine used to treat malaria.

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
- ▶ antiparasitics such as chloroquine, halofantrine, lumefantrine and pentamidine
- ▶ sodium oxybate used to treat narcolepsy
- ▶ levodopa, a medicine to treat Parkinson's disease
- ▶ certain drugs used in the treatment of Parkinson's disease such as amantadine, apomorphine, bromocriptine, entacapone, ropinirole, rotigotine, selegiline
- ▶ other anti-psychotic medicines used for mental disorders such as chlorpromazine, flupentixol, haloperidol and levomepromazine
- ▶ medicines for severe pain called opiates such as morphine or pethidine
- ▶ methadone used to treat addiction
- ▶ hydroxychloroquine a drug used to treat malaria
- ▶ medicines which help you sleep such as barbiturates and benzodiazepines
- ▶ pain-killers such as tramadol or codeine
- ▶ anaesthetics
- ▶ antihistamines such as promethazine which make you sleepy
- ▶ other medicines that are administered intravenously (into the vein) such as erythromycin, and spiramycin
- ▶ alcohol containing medicines.

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

Amisulpride with food, drink and alcohol

- ▶ take the solution with a drink that does not contain alcohol
- ▶ 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 or pharmacist for advice before taking this medicine.

Pregnancy

Amisulpride is not recommended during pregnancy and in women of childbearing potential not using effective contraception.

The following symptoms may occur in newborn babies, of mothers that have used Amisulpride in the last trimester (last three months of their pregnancy): shaking, muscle stiffness and/or weakness, involuntary body tremors, sleepiness, agitation, breathing problems, and difficulty in feeding or sucking. If your baby develops any of these symptoms contact your doctor immediately.

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 feel less alert, drowsy, sleepy or experience blurred vision 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).

Sodium: This medicine contains less than 1 mmol sodium (23 mg) per 12ml dose, that is to say essentially 'sodium-free'.

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 split into two separate doses.

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. Your doctor may reduce your dosage if you have kidney failure.

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

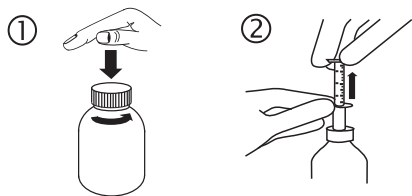
- ▶ do not stop treatment yourself
- ▶ this medicinal product must be taken orally
- ▶ take the solution with a drink that does not contain alcohol
- ▶ use the measuring syringe provided in the pack to deliver the required dose as prescribed by your doctor. Each 1ml solution contains 100mg of your medicine

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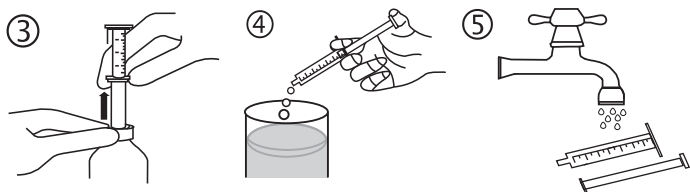
- ▶ if you feel the effect of your medicine is too weak or too strong, do not change the dose yourself, but ask your doctor.

Instructions for the use of syringe:

- Open the bottle: press the cap and turn it anticlockwise (Figure 1).
- 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).



- 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).
- 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

Do not take a double dose to make up for the dose you forgot to take. Take the next dose at the usual time.

If you have missed more than one dose, ask your doctor for advice.

If you stop taking Amisulpride

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.

The occurrence of rigidity of the muscles and disturbances of consciousness accompanied by an unexplained fever during treatment, requires immediate discontinuation of treatment and emergency medical attention.

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

Uncommon (affects less than 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 due to a decrease in the number of white blood cells (leukopenia or neutropenia).

Rare (may affect up to 1 in 1000 people)

- ▶ you have a very fast or an unusual heart rate, or chest pain which could result in a heart attack or life-threatening heart disorder
- ▶ during treatment, you have vision problems or headaches, tell your doctor immediately
- ▶ you get more infections than usual. This could be because of a blood disorder (agranulocytosis).

Not known (frequency cannot be estimated from available data)

- ▶ 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 (affects more than 1 in 10 people)

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

Common (affects less than 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 (affects less than 1 in 100 people)

- ▶ movements that you cannot control, mainly of the face or tongue.

Other side effects include:

Common (affects less than 1 in 10 people)

- ▶ abnormal eye muscle movements
- ▶ neck pain and/ stiffness
- ▶ 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
- ▶ difficulty in reaching an orgasm
- ▶ feeling dizzy (which can be due to low blood pressure)
- ▶ blurred vision.

Uncommon (affects less than 1 in 100 people)

- ▶ feeling confused
- ▶ nasal congestion
- ▶ high levels of fat (triglycerides) or cholesterol in the blood.
- ▶ increase in blood pressure
- ▶ difficulty passing water (urine)
- ▶ seizures (involuntary contractions of one or more muscles)
- ▶ hyperglycemia (excessive sugar in the blood)
- ▶ slow heart rate
- ▶ increase in liver enzymes, mainly transaminases
- ▶ damage to liver tissue
- ▶ decrease in density (osteopenia) and alteration of the structure of bone (osteoporosis) which may mean your bones are more likely to break
- ▶ allergic reactions
- ▶ disease of the lungs (pneumonia inhalation) can be manifested by inflammation, difficulty breathing, infection, cough (especially in combination with other depressants of the central nervous system)
- ▶ decrease in white blood cells (leukopenia or neutropenia)
- ▶ 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.

Rare (affects up to 1 in 1000 people)

- ▶ feeling unwell, confused or weak, feeling sick (nausea), loss of appetite, feeling irritable. This could be an illness called syndrome of inappropriate antidiuretic hormone secretion (SIADH)
- ▶ noncancerous benign pituitary tumor which may cause signs such as visual disturbances or headaches
- ▶ sudden swelling of the face and/or neck that can cause difficulty breathing and endanger the patient (angioedema), red patches on the skin itching (hives).

Not known (frequency cannot be estimated from available data)

- ▶ restless legs syndrome (overwhelming urge to move your legs, with symptoms getting worse at the end of the day)
- ▶ increased sensitivity of your skin to sun and ultraviolet light
- ▶ newborn withdrawal syndrome (see "Pregnancy, breast-feeding and fertility")
- ▶ swelling, pain and redness in the legs. Venous blood clots (especially in the legs) can travel via blood vessels to the lungs and cause pain in the chest and difficulty breathing
- ▶ 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'.

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 conditions.
- ▶ 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 60ml oral solution.

POM

Marketing Authorisation Holder and Manufacturer:

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

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