

# **PACKAGE LEAFLET: INFORMATION FOR THE USER**

## **Amisulpride 100mg/ml Oral Solution** **Amisulpride**

**Read all of this leaflet carefully before you start taking this medicine.**

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

**In this leaflet:**

1. What Amisulpride Oral Solution is and what it is used for
2. Before you take Amisulpride Oral Solution
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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).

#### **What this medicine does**

Amisulpride Oral Solution is one of a group of medicines called neuroleptics. These are used to treat acute and chronic schizophrenia. Symptoms of this condition can include sensing, seeing or hearing things that do not exist, becoming withdrawn and having mistaken beliefs or suspicions.

### **2. 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 (see section 6, **Further information**);
- if you have a tumour of the pituitary gland or breast cancer;
- if you have phaeochromocytoma (a tumour of the adrenal gland);
- if you are under 18 years of age;
- if you are breast-feeding;
- if you are taking a dopamine agonist e.g. levodopa used in Parkinson's disease, bromocriptine used in pituitary problems and ropinirole used in restless leg syndrome.

**Talk to your doctor or pharmacist if any of the following apply to you:**

- if you suffer from kidney problems;
- if you have a history of epilepsy;
- if you suffer from Parkinson's disease;
- if you are a diabetic or have been told you have an increased risk of having diabetes;
- if you are elderly. This is because elderly people would be more likely to get low blood pressure or feel sleepy;
- if you have heart disease, or a family history of heart problems;
- if you have had a stroke or your doctor has told you that you may be at risk from a stroke.

**Take special care with Amisulpride Oral Solution:**

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.

**Using other medicines**

Tell your doctor or pharmacist if you are taking any medicines listed under section 2,

**Do not take Amisulpride Oral Solution.**

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

- **medicines that act on the brain** (CNS depressants) including **anaesthetics**, **some antihistamines**, **medicines used to relieve pain** (narcotics), **medicines to help you sleep** (barbiturates, benzodiazepines), or **medicines that treat anxiety**;
- **clonidine** (used to treat high blood pressure, migraine and menopausal flushing) or **its derivatives**
- **medicines used to treat certain mental and emotional conditions** (antipsychotics);
- **medicines which lower your blood pressure** e.g. diltiazem;
- **medicines to treat an irregular heartbeat (arrhythmias)** e.g. quinidine, disopyramide, amiodarone or sotalol;
- **some medicines used to treat malaria or to help prevent you from catching malaria** e.g. mefloquine.

You must also inform your doctor or dentist that you are taking Amisulpride Oral Solution before you have an anaesthetic.

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

**Taking Amisulpride Oral Solution with food, drink and alcohol**

A carbohydrate rich (starchy/sugary) meal may adversely effect how this medicine works. Therefore you should take Amisulpride Oral Solution before a meal and at about the same time(s) each day. Do not drink alcohol whilst you are taking this medicine as the effects of alcohol may be increased.

**Pregnancy and breast-feeding**

- **Do not** take Amisulpride Oral Solution if you are breast-feeding.
- If you are a woman of child bearing age, you should talk to your doctor about the use of appropriate contraception while taking this medicine.

- If you are pregnant, or thinking of becoming pregnant, ask your doctor or pharmacist for advice before taking Amisulpride Oral Solution.

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

### **Driving and using machines**

When taking this medicine you may feel drowsy or find that your reaction time is impaired. **Do not** drive and **do not** use any tools or machines until you are sure that you are not affected.

### **Important information about some of the other ingredients in Amisulpride Oral Solution**

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

This medicinal product contains 0.17mmol (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**

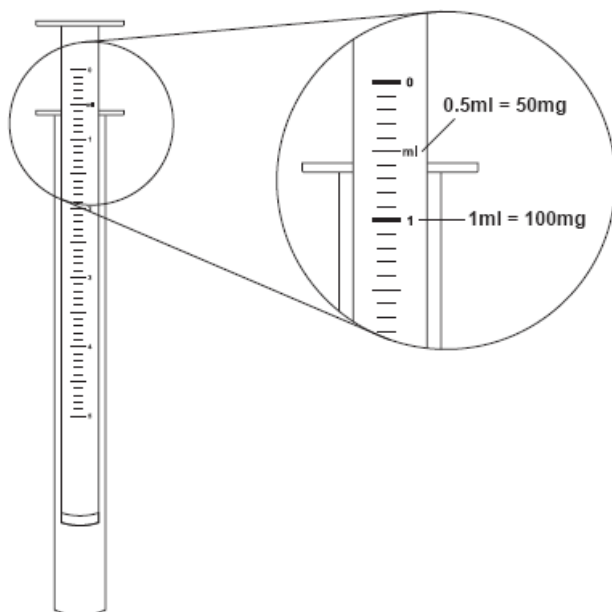
Your doctor will prescribe the most appropriate dose to treat your condition. Always take Amisulpride Oral Solution exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

- Take your medicine by mouth.
- Take your medicine with a drink that does not contain alcohol.
- Take before a meal.

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

### **Adults and the elderly**

- The usual dose is between 0.5ml (50mg amisulpride) and 8ml (800mg amisulpride) each day.
- This may be increased to 12ml (1200mg amisulpride) daily.
- Dosages up to 3ml (300mg amisulpride) can be taken once daily.
- Dosages greater than 3ml (300mg amisulpride) should not be taken all at once. Your doctor will tell you how much to take and when to take it.

In the elderly, Amisulpride Oral Solution may increase the risk of low blood pressure or may make you feel sleepier; therefore your doctor may want to monitor you more closely and may decide to reduce the dose you are taking.

### **Children under 18 years of age**

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

### **Patients with kidney problems**

- If you suffer from kidney problems, your doctor may choose to give you a lower dose of Amisulpride Oral Solution.

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

### **If you take more Amisulpride Oral Solution than you should**

If you or someone else takes more Amisulpride Oral Solution than has been prescribed, or you think a child has swallowed any Amisulpride Oral Solution, contact your doctor, pharmacist or hospital emergency department immediately and take your Amisulpride Oral Solution with you.

- Symptoms of overdose may include sleepiness, coma, low blood pressure, shaking, slowed movement, increased saliva, stiffness and restlessness.

### **If you forget to take Amisulpride Oral Solution**

- If you forget to take a dose, do not worry. Take the next dose when it is due.
- **Do not** take double the amount to make up for a forgotten dose.

### **If you stop taking Amisulpride Oral Solution**

- **Do not** stop taking Amisulpride Oral Solution suddenly as this may cause side effects.
- Speak to your doctor before you stop taking Amisulpride Oral Solution.
- Your doctor will tell you how to reduce your dose slowly over a number of weeks or months to help lower the chance of you getting withdrawal symptoms.
- Stopping Amisulpride Oral Solution suddenly can lead to **withdrawal symptoms** such as:
  - feeling or being sick
  - problems sleeping
  - feeling restless
  - unusual body movements or muscle stiffness
  - your original condition may come back

## **4. Possible side effects**

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

### **If you experience any of the following symptoms, contact your doctor immediately and stop taking this medicine:**

- 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 an unusual heart rate, very fast heart rate or chest pain which could result in a heart attack or life-threatening heart disorder.
- Severe allergic reaction (affecting fewer than 1 in 100 people). You may have a red lumpy rash, difficulty breathing, swelling of face, lips or eyelids, unexplained high temperature (fever) and feel faint. **If the swelling affects your throat and makes breathing and swallowing difficult, go to hospital straight away.**
- 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.

**If the following side effect occurs, speak to your doctor immediately.**

- You experience unexplained infections or fevers. This may be the result of lower white blood cell counts and your doctor may need to check your blood.

**Very common side effects (affecting more than 1 in 10 people):**

- Trembling, muscle stiffness, excess saliva, slowed movement or restlessness. Your doctor may give you another medicine to reduce these symptoms. The effects are generally mild at low doses.

**Common side effects (affecting up to 1 in 10 people):**

- Neck spasms, rolling of the eyes, lockjaw. Your doctor may give you another medicine to treat these symptoms
- Feeling drowsy
- Sleeplessness, agitation, anxiety
- Difficulty in reaching orgasm
- Problems with digestion such as constipation, feeling or being sick, dry mouth
- Weight gain
- Milk production from the breasts (in women), breast pain
- Stopping of menstrual periods
- Enlarged breasts in men
- Difficulty in getting, or maintaining, an erection (impotence)
- Feeling dizzy when you stand up if sitting, or sit up after lying down (which can be due to low blood pressure)

**Uncommon side effects (affecting fewer than 1 in 100 people):**

- Uncontrollable movements of the face or tongue (tardive dyskinesia)
- Seizures, convulsions. If you have a history of epilepsy your doctor will monitor you closely while taking this medicine as your seizure threshold may be reduced and you may experience more seizures
- Liver enzyme test changes (you may get increased levels of certain liver enzymes)
- High blood sugar (hyperglycaemia) which may result in the need to urinate more frequently, feeling tired, feeling thirsty or experiencing blurred vision
- Slowing of the heartbeat

**Other side effects:**

Rash (hives) or swelling of the skin

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

Pharmacovigilance Section, Irish Medicines Board, Dublin 2, Ireland

Tel: +353 1 6764971 Website: [www.imb.ie](http://www.imb.ie)

email: [imbpharmacovigilance@imb.ie](mailto:imbpharmacovigilance@imb.ie)

In elderly people with dementia, there has been a small increase in the number of deaths reported for patients taking antipsychotics compared with those not receiving antipsychotics.

## 5. How to store Amisulpride Oral Solution

Keep out of the reach and sight of children.

Do not use after the expiry date stated on the carton and the bottle label. 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 if you notice any visible signs of damage to the bottle or deterioration in your medicine. Return it to your pharmacist.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of 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. Further 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, caramel flavour (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.

### Marketing Authorisation Holder

Focus Pharmaceuticals Limited, Capital House, 85 King William Street, London EC4N 7BL, UK.

Tel: 00 44 (0)1283 495 280 Fax: 00 44 (0)1283 495 290

Email: [medinfo@focuspharma.co.uk](mailto:medinfo@focuspharma.co.uk)

### Manufacturer

One-Pharma S.A. 60<sup>th</sup> km of the Athens-Lamia Highway (Schimatari), Greece.

For any information about this medicinal product, please contact the Marketing Authorisation Holder, details provided above.

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

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