



PACKAGE LEAFLET:  
INFORMATION FOR THE USER

**Amisulpride  
50mg, 100mg, 200mg &  
400mg Tablets  
(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 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 or nurse. This includes any possible side effects not listed in this leaflet. see section 4.

**What is in this leaflet**

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

**1. WHAT AMISULPRIDE TABLETS ARE AND WHAT THEY ARE USED FOR**

Amisulpride belongs to a group of medicines called antipsychotics. The tablets are 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 tablets work 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 are pregnant, might become pregnant or are breast-feeding (see Pregnancy and breastfeeding section)
- If you have a prolactin dependent tumour or breast cancer
- If you have pheochromocytoma (a tumour on the adrenal gland)
- If you are under 18 years of age.
- If you are taking antiarrhythmic drugs for controlling the heart rhythm such as quinidine, disopyramide, procainamide, amiodarone, sotalol
- If you are taking bepridil (calcium channel blockers used for chest pain)
- If you are taking cisapride for gastrointestinal problems
- If you are taking sultopride used in schizophrenia
- If you are taking thioridazine used for schizophrenia and psychosis
- If you are taking IV erythromycin and sparflaxacin used in infections
- If you are taking IV vincamine used to improve blood flow in the brain
- If you are taking halofantrine used to treat malaria
- If you are taking pentamidine used in chest infections
- If you are taking levodopa, a medicine to treat Parkinson's disease (see 'Taking other medicines' section)
- If you have been diagnosed with a pituitary tumour.

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.

**Warning and precautions**

Please tell your doctor before you start to take your tablets:

- If you suffer from kidney disease
- If you have a history of epilepsy or seizures (fits)
- If you suffer from Parkinson's disease
- If you have an unusual heart rate (rhythm)
- If you have a slow heart beat (less than 5 beats per minute)
- If you have low potassium levels in your blood
- If you have a long QT interval (heart conduction problem)
- 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
- If you have a heart disease or family history of heart problems
- If your doctor have told you that you might have a stroke
- If you are diabetic or have been told you have an increased risk of having diabetes

- If you are elderly. This is because elderly people are 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.
- If you have a low number of white blood cells (agranulocytosis). This means you may get infections more easily than usual.
- If you have frequent infections such as fever, severe chills, sore throat or mouth ulcers. These could be signs of a blood problem called 'leukopenia'
- If you or someone else in your family has a history of breast cancer.
- If you have high levels of prolactin.

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**

Please inform your doctor or pharmacist if you are taking or have recently taken, any other medicine including those that you have bought without a prescription.

**Do not take this medicine and tell your doctor if you are taking any of the following medicines:**

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

**Tell your doctor BEFORE starting your medicine if you are taking any of the following:**

- Medicines to reduce your heart rate such as quinidine, dysopyramide, amiodarone and sotalol
- medicines for high blood pressure and heart problems such as diltiazem, verapamil, guanfacine or digitalis
- clonidine used for migraines, flushing or for high blood pressure
- other anti-psychotic medicines used for mental problems
- medicines for severe pain called opiates such as morphine and pethidine
- pain-killers such as tramadol and indometacin
- mefloquine, medicine used to treat malaria
- medicines to help you sleep such as barbiturates and benzodiazepines
- anaesthetics
- anti-histamines such as promethazine which make you sleepy
- Clozapine used to treat schizophrenia
- medicines which induce hypokalaemia such as hypokalaemic diuretics, stimulant laxatives, IV amphotericin B, glucocorticoids or tetracosactides
- Neuroleptics such as pimozide, haloperidol, imipramine, antidepressants or lithium

**Amisulpride Tablets with food and drink**

Do not drink alcohol while you are taking Amisulpride Tablets. This is because it can affect the way how the medicine works.

**Pregnancy and breast-feeding:**

Do not take this medicine if you are breast-feeding or planning to breast-feed

The following symptoms may occur in newborn babies, of mothers that have used Amisulpride tablets 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.

Talk to your doctor before taking this medicine if you are pregnant, might become pregnant or think you may be pregnant.

**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.

**Important information about some of the ingredients of Amisulpride Tablets**

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.

**3. HOW TO TAKE AMISULPRIDE TABLETS**

**Always take your tablets exactly how your doctor has told you to.** You should check with your doctor or pharmacist if you are not sure. Swallow the tablets whole with a glass of water.

The usual oral dose for:

**Adults**

The usual dose is between 50mg and 800mg each day. Your doctor may start a lower dose if necessary. If necessary your doctor can prescribe up to 1200mg each day. Doses up to 300mg each day can be taken as a single dose. Take the dose at the same time each day. doses above 300mg should be taken as half in the morning and half in the evening

**Elderly** is to be used with caution due to the risk of low blood pressure or sedation. Follow the doctor's instructions.

**Patients with kidney problems** Your doctor may need to give you a lower dose.

**Children under 18 years of age**

Amisulpride tablets should not be given to children under 18 years of age

P15XXXXX



#### **If you take more Amisulpride Tablets than you should**

It is important to take your medicine exactly as your doctor have prescribed. If you or someone else swallows several of these tablets all together, contact your doctor or hospital emergency department immediately. Always take any tablets and the container with you as this will allow easier identification of the tablets. 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 to take a dose, take it as soon as you remember. If it is almost time for your next dose, do not take double the dose, just carry on as before. Do not take a double dose to make up for a forgotten dose.

#### **If you stop taking Amisulpride Tablets**

Keep taking Amisulpride Tablets until doctor tells you to stop.

Do not stop taking Amisulpride Tablets if you feel better. It is important to keep taking your tablets unless your doctor tells you to stop.

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 restless
- muscle stiffness or unusual body movements
- your original condition may come back.

#### **Blood tests**

Taking Amisulpride Tablets 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, Amisulpride Tablets 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:**

#### **Common (may affect up to 1 in 10 people)**

- You have an unusual heart rate.

#### **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 difficulties, swelling of the lips, face, throat or tongue
- 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).
- you have fit (seizure)

#### **Rare (may affect up to 1 in 1000 people)**

- You have a high temperature, sweating, stiff muscles, fast heart beat, 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 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 and 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 ejaculation
- 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)

#### **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

#### **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: [www.mhra.gov.uk/yellowcard](http://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 store above 25°C
- Store in the original package.
- Do not use after the expiry date on the carton, the expiry date refers to the last day of the month.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

### **6. CONTENTS OF THE PACK AND OTHER INFORMATION**

#### **What Amisulpride Tablets contain:**

The **active** ingredient is amisulpride.

Each 50mg tablet contains 50mg of amisulpride.  
Each 100mg tablet contains 100mg of amisulpride.  
Each 200mg tablet contains 200mg of amisulpride.  
Each 400mg tablet contains 400mg of amisulpride.

The other substances for Amisulpride 50mg, 100mg & 200mg Tablets are maize starch, lactose monohydrate, methylcellulose 400cps, colloidal anhydrous silica and magnesium stearate.

The other substances in Amisulpride 400mg Tablets are lactose monohydrate, sodium starch glycolate, magnesium stearate, microcrystalline cellulose, methylcellulose 400cps, basic butylated methacrylate copolymer, titanium dioxide (E171), talc and macrogol 6000.

#### **What Amisulpride Tablets look like and contents of the pack**

##### **Amisulpride 50mg, 100mg & 200mg Tablets**

White to off-white, round, scored, uncoated tablets with 50, MAM100 and MAM200 marked on one side respectively.

##### **Amisulpride 400mg Tablets**

White to off-white, ovoidal shaped, biconvex, scored, film coated tablets marked MAM400 on one side.

Amisulpride 50mg, 100mg, 200mg & 400mg Tablets are available in blister packs of 60 tablets.

#### **Marketing Authorisation Holder and Manufacturer**

##### **Marketing Authorisation Holder:**

Milpharm Limited  
Ares, Odyssey Business Park,  
West End Road,  
South Ruislip, HA4 6QD,  
United Kingdom

##### **Manufacturers:**

Milpharm Limited  
Ares, Odyssey Business Park,  
West End Road,  
South Ruislip, HA4 6QD  
United Kingdom,

APL Swift Services (Malta) Ltd.,  
HF26, Hal Far Industrial Estate,  
Hal Far, Birzebbugia BBG 3000

PL16363/0145

PL16363/0146

PL16363/0147

PL16363/0148

**This leaflet was last revised in 10/2018 POM**