PATIENT INFORMATION LEAFLET

AMISULPRIDE 50MG, 100MG, 200MG AND 400MG TABLETS

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.
- Your doctor may have given you this medicine before from another company. It may have looked slightly different. However, either brand will have the same effect.

In this leaflet:

1. What amisulpride is and what it is used for
2. Before you take amisulpride
3. How to take amisulpride
4. Possible side effects
5. How to store amisulpride
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1. What amisulpride is and what it is used for

The name of your medicine is Amisulpride 50mg, 100mg, 200mg or 400mg Tablets (called amisulpride throughout this leaflet). This belongs to a group of medicines 'anti-psychotics'.
It is used to treat schizophrenia.

How Amisulpride works
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.

2. Before you take amisulpride

Do not take amisulpride and tell your doctor if:
X You are allergic (hypersensitive) to amisulpride or any of the other ingredients of amisulpride (listed in Section 6 below).
X Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
X You are pregnant, might become pregnant or are breast-feeding (see 'Pregnancy and breast-feeding' section below).
X You have breast cancer or something called 'a prolactin dependent tumour'.
X You have a tumour on your adrenal gland (called phaeochromocytoma).
X You have been diagnosed with a pituitary tumour.
X The patient is under 18 years old.
X Do not take if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking amisulpride.

Warnings 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.

Take special care and check with your doctor before taking amisulpride if:
- You have kidney problems.
- You have diabetes. Your diabetes may need careful monitoring.
- You have Parkinson's disease.
- You have ever had fits (epileptic seizures).
- You have an unusual heart rate (rhythm).
- You are elderly. This is because elderly people are more likely to get low blood pressure or feel sleepy.
- You have low potassium levels in your blood.
- You are taking any drugs which may lower potassium levels (such as thiazide, diuretics, bendroflumethiazide, hydrochlorothiazide).
- You have been told by your doctor 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 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.

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 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.

Do not take this medicine, and tell your doctor, if you are taking:
- 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 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 high blood pressure and migraine such as clonidine, diltiazem and verapamil, guanfacine and digitalis.
- Mefloquine used to treat malaria.
- Medicines which help you sleep such as barbiturates and benzodiazepines.
- Pain-killers such as tramadol and indomethacin.
- Anaesthetics.
- Antihistamines such as promethazine which make you sleepy.
- Medicines that can affect the levels of sodium and potassium in your blood, such as water tablets, some laxatives, glucocorticoids, tetracosactide and amphotericin.

Taking amisulpride with food and drink
- Swallow amisulpride tablets with plenty of water before a meal.
- Do not drink alcohol while you are taking amisulpride. This is because amisulpride can change the way the alcohol affects you.

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 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
This medicine contains less than 1mmol sodium (23mg) per dose, that is to say essentially 'sodium free'.
Amisulpride contains 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

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

Taking this medicine
- Swallow the tablets whole with a drink of water.
- Take before a meal.

How much to take:
Adults and children
- The usual dose is between 50mg and 800mg each day.
- Your doctor may start you on 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 half in the morning and half in the evening.
- If you have kidney problems your doctor may prescribe you a lower dose.
- Elderly people may be prescribed a lower dose. This is because amisulpride may make you feel sleepy or lower your blood pressure which could make you feel dizzy, light headed or faint.

Children
This medicine is not recommended in people under 18 years old.

If you take more amisulpride than you should
If you take more tablets 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
If you forget to take a dose at the right time, take it as soon as you remember, then go on as before. However, do not take a double dose to make up for a forgotten tablet.

If you stop taking amisulpride
Keep taking amisulpride until your doctor tells you to stop. Do not stop taking your medicine just because you feel better as your illness may get worse or come back. Unless your doctor tells you otherwise, amisulpride should not be stopped suddenly as this may cause withdrawal effects such as muscle stiffness or unusual body movements.

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 about this medicine, 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:

Uncommon side effects (may affect up to 1 in 100 people)
- You get swelling of the hands, feet, ankles, face, lips or throat which may cause difficulty in swallowing or breathing. You could also notice an itchy, lumpy rash (hives) or nettle rash (urticaria). This may mean you are having an **allergic reaction** to amisulpride tablets.
- 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 side effects (may affect up to 1 in 1000 people)
- You have a very fast or unusual heart rate or chest pain. These could be signs of a heart attack or life-threatening heart disorder.
- 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 side effect called 'neuroleptic malignant syndrome'.
- 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 side effects (may affect more than 1 in 10 people)
- Trembling, muscle stiffness or spasm, slow movement, producing more saliva than usual or feeling restless. (These symptoms can be reduced if your doctor lowers your dose of amisulpride or prescribes an additional medicine).

Common side effects (may affect up to 1 in 10 people)
- Movements that you cannot control, mainly of your arms and legs (this will usually be reduced if your dose of amisulpride is lowered by your doctor or if your doctor prescribes you an additional medicine).

Uncommon side effects (may affect up to 1 in 100 people)
- Movements that you cannot control, mainly of your face or tongue.

Other side effects include:

Common side effects (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 side effects (may affect up to 1 in 100 people)
- High blood sugar (hyperglycaemia)
- Slowing of the heart beat
- 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 side effects (may affect up to 1 in 1000 people)
- Noncancerous benign tumour (such as prolactinoma).
- Feeling unwell, confused and/or weak, feeling sick (nausea), loss of appetite, feeling irritable. This could be something 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 (an uncomfortable feeling in the legs, temporarily relieved by movement and with symptoms getting worse at the end of the day)
- Increased sensitivity of your skin to sun and ultraviolet light.

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

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. 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

- Keep this medicine in a safe place where children cannot see or reach it.
- Do not use amisulpride after the expiry date which is stated on the carton.
- 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. Further information

What Amisulpride 50mg, 100mg, 200mg or 400mg Tablets contain
Each tablet contains 50mg, 100mg, 200mg or 400mg of amisulpride as the active substance. The other ingredients are, lactose monohydrate, microcrystalline cellulose, sodium starch glycolate, hypromellose and magnesium stearate. The 400mg tablet also contains macrogol ester and titanium dioxide (E171).

What amisulpride looks like and contents of the pack
- Amisulpride 50mg Tablets are white to off-white, round, flat-faced tablets engraved AMI 50 on one side. They are supplied in blister packs of 60 tablets.
- Amisulpride 100mg Tablets are white to off-white, round, flat-faced tablets engraved AMI 100 on one side and a breakline on the other side. They are supplied in blister packs of 60 tablets.
- Amisulpride 200mg Tablets are white to off-white, round, flat-faced tablets engraved AMI 200 on one side and a breakline on the other side. They are supplied in blister packs of 60 tablets.
- Amisulpride 400mg Tablets are white, film-coated, oblong scored, engraved "AMI 400". They are supplied in blister packs of 60 tablets.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder is:
Zentiva Pharma UK Limited, 12 New Fetter Lane, London, EC4A 1JP, United Kingdom

Manufacturer is:
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