Package leaflet: Information for the patient

Amisulpride 50 mg, 200 mg Tablets
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.

What is in this leaflet

1. What Amisulpride is and what it is used for

Amisulpride contains amisulpride and belongs to a group of medicines called antipsychotics, which help to control the symptoms of a mental illness called schizophrenia.

Symptoms include:
- delusions (having strange or unusual thoughts)
- hallucinations (seeing or hearing things that are not there)
- being suspicious or aggressive for no apparent reason (these are so called "positive symptoms")
- becoming withdrawn and subdued (these are so called "negative symptoms").

Amisulpride can be used at the start of and for the long term treatment of schizophrenia.

2. What you need to know before you take Amisulpride

Do not take Amisulpride if you:
- are allergic to amisulpride or any of the other ingredients of this medicine (listed in Section 6). Signs of an allergic reaction may include a rash, difficulty swallowing or breathing, swelling of the lips, face, throat or tongue
- have breast cancer or something called a ‘prolactin dependent tumour’.
- have a tumour on the adrenal gland called phaechromocytoma.
- are taking levodopa (used to treat Parkinson's disease) or medicines to treat heart rhythm disorders, or medicines that may cause an abnormal heart rhythm when used at the same time as amisulpride (see “Other medicines and Amisulpride” below)
- are 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.

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 discoloration of the eyes or skin.

Neuroleptic malignant syndrome (NMS) has been reported to occur with the use of antipsychotics. Contact a doctor or go to a hospital immediately if you notice the following side effects: unexplained high temperature, stiff muscles, clouded consciousness, muscle pain, sweating, fast heartbeat, fast breathing, feeling confused, drowsy or agitated.
Elevated creatinine phosphokinase (CPK) blood levels has also known to occur with NMS.

Talk to 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 are diabetic or have been told you have an increased risk of developing diabetes
- you have an unusual heart rate (rhythm)
- you have heart disease or family history of heart problems or sudden death
- you have a long QT interval or a history of this in the family (this is a measure of the way your heart is working and can be detected by a doctor using an electrocardiogram)
- you had a stroke previously or your doctor has told you that you are at risk of 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 or someone else in your family has a history of breast cancer, as amisulpride can affect the risk of developing breast cancer. You should therefore be closely monitored during treatment with Amisulpride
- you have a slow heartbeat (less than 55 beats per minute)
- you are taking other medicines that could affect your heart's function: check with your doctor before taking any other medicine. See also under headings "Do not take Amisulpride" and "Other medicines and Amisulpride"
- you have been told you have a low amount of potassium or magnesium in your blood.
- 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 in patients taking antipsychotics compared to those not receiving antipsychotics.

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

Other medicines and Amisulpride
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

This is because amisulpride can affect the way some other medicines work. Also some medicines can affect the way amisulpride works.

You should never take this medicine with cabergoline, quinagolide (medicines used for lactation disorders), citalopram, escitalopram (medicines to treat anxiety or depression), domperidone (medicine to

treat nausea and vomiting), hydroxyzine (medicine to treat anxiety or hives), or piperaquine (medicine to treat malaria).

In particular, **do not take this medicine and tell your doctor if you are taking**:

- bromocriptine, amantadine, apomorphine, entacapone, lisuride, pergolide, piribedil, pramipexole, rasagiline, rotigotine, selegiline, tolcapone or ropinirole (medicines used to treat Parkinson's disease)
- levodopa, a medicine to treat Parkinson's disease
- medicines to treat heart rhythm problems (such as quinidine, hydroquinidine, disopyramide, procainamide and class III antiarrhythmics such as amiodarone, dronedarone, sotalol, dofetilide and ibutilide)
- sodium oxybate (used to treat narcolepsy),
- cisapride (used to treat stomach problems)
- bepridil (used to treat angina/chest pain and changes in heart rhythm)
- sultopride or thioridazine (for schizophrenia)
- methadone (for pain and drug abuse)
- chloroquine, lumefantrine or halofantrine (to prevent malaria)
- pentamidine (to treat infections in HIV patients)
- erythromycin by injection or sparfloxacin (antibiotics)
- medicines for fungal infections, such as clotrimazole
- vincamine by injection (used for various brain disorders)
- other medicines such as: arsenious, diphemanil, dolasetron IV, hydroxychloroquine, levofloxacin, mequitazine, mizolastine, prucalopride, moxifloxacin, spiramycin IV, toremifene or vandetanib,

Tell your doctor if you are taking any of the following medicines:

- medicines used to treat high blood pressure or other heart problems that could slow your heart rate down. These include beta-blockers (such as nebivolol or bisoprolol), diltiazem, verapamil, clonidine, guanfacine, digoxin or digoxin-like medicines
- medicines which can cause low potassium levels including diuretics ("water tablets"), some laxatives, amphotericin B (by injection), glucocorticoids (used for conditions such as asthma or rheumatoid arthritis) and tetracosactide (may be used in clinical investigations)
- medicines for psychiatric disorders such as chlorpromazine, cyamemazine, droperidol, flupenthixol, fluphenazine, levomepromazine, pipamperone, pipotiazine, sulpiride, sultopride, tiapride or zuclopenthixol
- medicines used to treat schizophrenia such as pimozide, clozapine or haloperidol
- imipramine or lithium (used to treat depression)
- some antihistamines such as astemizole and terfenadine (for allergies)
- mefloquine used to treat malaria
- ondansetron
- orlistat (used to treat obesity)
- other anti-psychotic medicines used for mental health problems
- medicines for severe pain called opiates such as morphine or pethidine
- medicines which help you sleep such as barbiturates and benzodiazepines
- pain-killers such as tramadol and indomethacin
- anaesthetics
- antihistamines (for allergies) which make you sleepy, such as promethazine
- medicines containing alcohol

Amisulpride with alcohol

Do not drink alcohol while you are taking Amisulpride. This is because Amisulpride can increase the effects of alcohol.

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.
The following symptoms may occur in newborn babies of mothers that have used Amisulpride in the last trimester (last three months of 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.

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 and have blurred vision while taking this medicine.
If this happens, do not drive or use any tools or machines.

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 medicine.

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.

Adults
If you suffer from positive symptoms, the recommended dose is between 400 mg and 800 mg daily, and will be adjusted by your doctor depending on the nature and severity of your illness and your kidney function. The maximum daily dose is 1,200 mg.

If you suffer from both positive and negative symptoms, your doctor will adjust your dose so that there is adequate control of the positive symptoms. To maintain treatment, your doctor will use the lowest possible dose that is effective for you.

If you suffer from mostly negative symptoms, the recommended dose is between 50 mg and 300 mg daily, and will be adjusted by your doctor depending on the nature and severity of your illness and your kidney function.

Patients over 65 years:
Amisulpride can cause sedation (drowsiness) or a fall in blood pressure, and is not generally recommended as there is only limited experience in this age group.

Use in children and adolescents:

Efficacy and safety of amisulpride in children and adolescents under 18 years of age have not been established. If absolutely required, treatment of adolescents from 15 to 18 years of age must be initiated and performed by a doctor experienced in treating schizophrenia in this age group.
Children and adolescents under 15 years of age must not take these tablets (see section 2 "Do not take Amisulpride").

Patients with kidney problems
Your doctor will normally give you a lower dose. This may be half or a third of the usual daily dose, depending on how well your kidneys are working.

How to take this medicine:
- Swallow the tablets with a glass of water.
- You can take them during or between meals.
- Doses up to 300 mg per day can be taken as a single dose preferably at the same time each day.
- Doses above 300 mg should be taken as half in the morning and half in the evening.
- The 200 mg tablets can be divided into equal doses

If you take more Amisulpride than you should
Contact your doctor or hospital immediately. Take the tablets, leaflet and/or carton with you 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.

If you forget to take Amisulpride
Take it as soon as you remember. 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 tablet.

If you stop taking Amisulpride
Keep taking your tablets until your doctor tells you to stop. Do not stop taking them just because you feel better. If you stop, your illness may get worse or come back. Unless your doctor tells you to, stopping treatment suddenly may cause withdrawal effects such as feeling sick, vomiting, sweating, difficulty sleeping, extreme restlessness, muscle stiffness or abnormal movements, or your original condition may come back. To avoid such effects it is important to reduce the dose gradually according to your doctor's instructions.

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

4. Possible side effects

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

Contact a doctor or go to a hospital immediately if you notice any of the following side effects:

Uncommon (may affect up to 1 in 100 people)
- A serious allergic reaction. The signs may include an itchy, lumpy rash, difficulty swallowing or breathing, swelling of your lips, face, throat or tongue
- A fit (seizure)
- You get more infections than usual, causing fever, sore throat or mouth ulcers. This could be because of a decrease in the number, or lack of white blood cells.

Rare (may affect up to 1 in 1,000 people)

- High temperature, blurred vision, 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'
- An unusual heart rate, very fast heart rate or chest pain which could result in a heart attack or life-threatening heart disorder.
- 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 signs seek medical advice immediately.
- Benign (non-cancerous) pituitary tumour such as prolactinoma.
- 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).

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 head, neck, jaw or eyes.

Uncommon (may affect up to 1 in 100 people)

- Movements that you cannot control, mainly of the face or tongue
- Osteoporosis (condition, when your bones are more likely to break) or osteopenia (bone weakening)
- Aspiration pneumonia (a type of lung infection that occurs when food, saliva, liquids, or vomit is breathed into the lungs or airways leading to the lungs, instead of being swallowed into the esophagus and stomach.

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
- Low blood pressure, which may cause you to feel dizzy
- Difficulty reaching orgasm
- Blurred vision.
- Increased blood levels of prolactin (a protein), which would be seen in a test and may cause:
    - Breast pain or enlargement, unusual production of breast milk (these can occur in women and men).
    - Menstrual problems such as missed periods.
    - Difficulty in getting or maintaining an erection.

Uncommon (may affect up to 1 in 100 people)

- Slowing of the heart beat
- High blood sugar (hyperglycaemia).
- Raised levels of certain fats (triglycerides) and cholesterol in the blood.

- Increase in liver enzymes, which would be seen in a blood test
- Confusion.
- Increase in blood pressure
- Stuffy nose.
- Urinary retention (if you are not able to completely empty your bladder)
- Liver tissue damage

Rare (may affect up to 1 in 1,000 people)
- Low levels of sodium in your blood which may be seen in blood tests (hyponatraemia).

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).
- Increased sensitivity of your skin to sun and ultraviolet light.
- Withdrawal symptoms seen in newborn babies where the mother has taken this medicine.
- Falls due to reduced ability to maintain body balance, sometimes resulting in fractures.
- Rhabdomyolysis (muscle breakdown associated with muscle pain).
- Increased levels of creatine phosphokinase (blood test indicating muscle damage).

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 HPRA Pharmacovigilance, Website: www.hpra.ie. 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 blister after 'EXP'.
The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

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 protect the environment.

6. Contents of the pack and other information

What Amisulpride contains
The active substance is amisulpride.
Each 50 mg tablet contains 50 mg amisulpride.
Each 200 mg tablet contains 200 mg amisulpride.

The other ingredients are lactose monohydrate (see section 2, 'Amisulpride contains lactose'), microcrystalline cellulose, sodium starch glycolate (Type A), hypromellose, magnesium stearate.

What Amisulpride looks like and contents of the pack
50mg: White round tablet with 'AA 50' on one side and 'G' on the reverse, 6 mm in diameter.
200 mg: White round tablet with 'AMI' breakline '200' on one side and 'G' on the reverse, 10 mm in diameter.

Amisulpride is available in:
Blister packs containing:
12 tablets (50mg)
20 tablets (50mg, 200mg)
30 tablets (50mg, 200mg)
50 tablets (50mg, 200mg)
60 tablets (50mg, 200mg)
60x1 tablets (200mg)
90 tablets (50mg, 200mg)
100 tablets (50mg, 200mg)
120 tablets (200mg)
150 tablets (200mg)
150 (3 cartons of 50) tablets (200 mg)

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Viatris Limited,
Damastown Industrial Park,
Mulhuddart,
Dublin 15,
DUBLIN,
Ireland.

Manufacturer
Mylan Hungary Kft./Mylan Hungary Ltd., Mylan utca 1., Komárom, 2900 , Hungary

This medicinal product is authorised in the Member States of the EEA under the following names:

Czech Republic	Amisulprid Viatris
France	Amisulpride Viatris 100 mg, comprimé sécable
	Amisulpride Viatris 200 mg, comprimé sécable
	Amisulpride Viatris 400 mg, comprimé pelliculé sécable
Germany	Amisulprid Mylan 100, 200 mg Tabletten
	Amisulprid Mylan 400 mg Filmtabletten
Ireland	Amisulpride 50 mg, 200 mg Tablets
Italy	Amisulpride Mylan 50, 200, 400mg
Portugal	Amissulprida Mylan
Slovakia	Amisulprid Viatris 50 mg, 100 mg, 200 mg tablety
	Amisulprid Viatris 400 mg filmom obalené tablety
United Kingdom	Amisulpride 50, 100, 200 mg tablets
	Amisulpride 400 mg film-coated tablets

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