

BOZZA N°	01 15.03.21	02 17.05.21								
-----------------	----------------	----------------	--	--	--	--	--	--	--	--

Font e size utilizate:
Times New Roman bold / regular: c. 7,6/9,12 - c. 14,6/17 - c. 10,28/14,5
Amisulpride_Rivopharm_Tablets Leaflet Fto: 130x 480 mm

PACKAGE LEAFLET: INFORMATION FOR THE USER

Amisulpride 50 mg tablets
Amisulpride 100 mg tablets
Amisulpride 200 mg tablets
Amisulpride 400 mg film-coated tablets



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 n 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

The name of your medicine is Amisulpride 50 mg tablets, Amisulpride 100 mg tablets, Amisulpride 200 mg tablets or Amisulpride 400 mg film-coated tablets (called Amisulpride tablets throughout this leaflet).

The active ingredient in this medicine is amisulpride. This belongs to a group of medicines called ‘anti-psychotics’. It is 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 works 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 and tell your doctor:

- 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 breast-feeding’ section)
- if you have breast cancer or something called ‘a prolactin dependent tumour’
- if you have a tumour on the adrenal gland (called pheochromocytoma)
- if you are taking levodopa, a medicine to treat Parkinson’s disease (see ‘Taking other medicines’ section)
- You have been diagnosed with a pituitary tumour.
- The patient is under 18 years of age

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.

Take special care with Amisulpride tablets

Check with your doctor or pharmacist before taking your medicine:

- if you have kidney problems
- if you have Parkinson’s disease
- if you have ever had fits (epileptic seizures)
- if you have an unusual heart rate (rhythm)
- if you have heart disease or family history of heart problems
- if your doctor has told you that you might have a stroke
- 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 are diabetic or have been told you have an increased risk of having diabetes
- if you have a slow heart beat (less than 55 beats per minute)
- if you have been told you have a low amount of potassium in your blood.
- if you are elderly. This is because elderly people would be 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
- You have high levels of prolactin.

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.

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 tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take 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:

- 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 severe pain called opiates such as morphine or pethidine
- Medicines for high blood pressure and heart problems such as diltiazem, verapamil, guanfacine and digitalis
- Clonidine used for migraines, flushing or high blood pressure
- 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

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

Amisulpride tablets with food, drink and alcohol

- Swallow Amisulpride tablets with plenty of water before a meal
- Do not drink alcohol while you are taking Amisulpride. This is because it can affect the way the medicine works

Pregnancy and 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 Tablets are not recommended during pregnancy and in women of childbearing potential not using effective contraception. If you use Amisulpride Tablets 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.

Breast-feeding

You should not breast-feed during therapy with Amisulpride Tablets. Talk to your doctor about the best way to feed your baby if you are taking Amisulpride Tablets.

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.

Amisulpride tablets contain lactose, a type of sugar. If you have been told by your doctor that you cannot tolerate some sugars, talk to your doctor or pharmacist before taking this medicinal product.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially ‘sodium-free’.

3. HOW TO TAKE AMISULPRIDE TABLETS

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Taking this medicine

- Take this medicine by mouth
- Swallow the tablets whole or halved with a drink of water.
Do not chew your tablets
- Take before a meal
- If you feel the effect of your medicine is too weak or too strong, do not change the dose yourself, but ask your doctor
- If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product

How much to take

The amount of Amisulpride you take will depend on your illness. Follow your doctor’s instructions carefully.

Adults

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

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

People with kidney problems

Your doctor may need to give you a lower dose



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

If you take more Amisulpride tablets 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, low blood pressure, feeling drowsy or sleepy which could lead to a loss of consciousness.

If you forget to take Amisulpride tablets

If you forget a dose, take it as soon as you remember it. 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 dose.

If you stop taking Amisulpride tablets

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, this medicine 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:

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 problems, swelling of your lips, face, throat or tongue.
- 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 (may affect up to 1 in 1000 people)

- 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 a very fast or unusual 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 tablets or prescribes an additional medicine).

Uncommon (may affect up to 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)

- 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 (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)
- Liver tissue damage

Rare (may affect up to in 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.

Not known (frequency cannot be estimated from 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.

Tell your doctor or pharmacist if any of the side effects get serious or lasts longer than a few days, or if you notice any side effects not listed in this leaflet.

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 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 TABLETS

Keep this medicine out of the sight and reach of children.

This medicinal product does not require any special storage conditions.

Do not use this medicine after the expiry date, which is stated on the carton and blisters after 'EXP'. The expiry date refers to the last day of that month.

Do not use this medicine if you notice that the tablets become discoloured.

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 tablets contain

The Amisulpride 50 mg tablets contain 50 mg of the active substance, amisulpride.

The Amisulpride 100 mg tablets contain 100 mg of the active substance, amisulpride.

The Amisulpride 200 mg tablets contain 200 mg of the active substance, amisulpride.

The Amisulpride 400 mg film-coated tablets contain 400 mg of the active substance, amisulpride.

The other ingredients in Amisulpride are: lactose monohydrate, methylcellulose, sodium starch glycolate (Type A), microcrystalline cellulose, magnesium stearate.

Amisulpride 400 mg tablets also contain Eudragit (E100), titanium dioxide (E171), talc, magnesium stearate, Macrogol 6000.

What Amisulpride tablets look like and contents of the pack

Amisulpride 50 mg tablets are white, round, biconvex tablets with a break line on one side and embossed with A50 on the other side. They are available in blister packs of 60 tablets.

Amisulpride 100 mg tablets are white, round, flat tablets with break line on one side and embossed with A100 on the other side. They are available in blister packs of 60 tablets.

Amisulpride 200 mg tablets are white, round, flat tablets with break line on one side and embossed with A200 on the other side. They are available in blister packs of 60 tablets.

Amisulpride 400 mg tablets are white to off white, film-coated, oblong tablets with break line on one side. They are available in blister packs of 60 tablets.

Marketing authorisation holder and manufacturer

Marketing Authorisation Holder

Rivopharm UK Limited
30th Floor, 40 Bank Street
Canary Wharf
London E14 5NR

Manufacturers

Laboratoires BTT
ZI de Krafft
67150 Erstein
France

Rivopharm UK Limited
30th Floor, 40 Bank Street
Canary Wharf
London E14 5NR

This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

This leaflet was last revised in 05/2021

 **Rivopharm**