

## **Package leaflet: information for the user**

Amisulpride Mylan 400mg film-coated 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 Mylan is and what it is used for
2. What you need to know before you take Amisulpride Mylan
3. How to take Amisulpride Mylan
4. Possible side effects
5. How to store Amisulpride Mylan
6. Contents of the pack and other information

### **1. What Amisulpride Mylan is and what it is used for**

Amisulpride Mylan contains a medicine called amisulpride. This belongs to a group of medicines called 'antipsychotics'. It is used in the treatment of acute and chronic schizophrenic disorders. This condition causes symptoms such as becoming withdrawn, sensing, seeing or hearing things which do not exist, mistaken beliefs or unfounded suspicions. Sometimes people with these symptoms may also feel tense, anxious or depressed.

Amisulpride Mylan also acts on mood disorder in the sense of depression.

### **2. What you need to know before you take Amisulpride Mylan**

#### **Do not take Amisulpride Mylan**

- If you are allergic to amisulpride or any of the other ingredients of this medicine (listed in section 6)
- if you notice signs of an allergic reaction including: a rash, swelling or breathing problems, swelling of your lips, face, throat or tongue
- if you have a prolactin dependent tumour or breast cancer
- if you have pheochromocytoma (a tumour on the adrenal gland)
- If you are pregnant, might become pregnant or are breast-feeding (see Pregnancy and breast-feeding section)
- if you
  - Are taking levodopa (used to treat Parkinson's disease)
- if the patient is under 18 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 Mylan.

### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Amisulpride Mylan if you:

- are an elderly patient as elderly people are more likely to get low blood pressure and feel sleepy. A small increase in the number of deaths of elderly people with dementia has been reported for patients taking anti-psychotics compared to those not receiving anti-psychotics
- or someone else in your family has a history of blood clots, as medicines like these have been associated with formation of blood clots
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- have kidney problems
- have Parkinson's disease (taking this medicine may worsen your condition)
- have a history of fits (epileptic seizures)
- have an abnormal heart rate or rhythm
- have a slow heart beat (less than 55 beats per minute)
- have heart disease or family history of heart problems
- have diabetes mellitus or at risk of having it
- have been told by your doctor that you are at risk of having stroke
- have been told you have a low amount of potassium in your blood
- have a low number of white blood cells (this means you may get infections more easily than usual)
- have frequent infections such as fever, severe chills, sore throat or mouth ulcers. These could be signs of a blood problem called leucopenia

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

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Contact your doctor immediately if you suddenly develop a high temperature (please refer to section 4).

### **Children and adolescents**

Amisulpride Mylan should not be given to children under 18 years old.

### **Other medicines and Amisulpride Mylan**

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

In particular, 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 (medicines used to treat Parkinson's disease)

Amisulpride Mylan can interact with the following medicines:

- Anaesthetics
- Antihistamines (which cause drowsiness)
- Medicines used to control your heart beat such as quinidine, disopyramide, amiodarone and sotalol
- 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 indometacin

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

Please refer to “**Do not take Amisulpride Mylan**” in addition.

### **Amisulpride Mylan with alcohol**

Do not drink alcohol while you are taking Amisulpride Mylan, it may make you drowsy.

### **Pregnancy and breast-feeding**

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.

Due to very limited clinical data, Amisulpride Mylan should not be taken during pregnancy and breast-feeding.

The following symptoms may occur in newborn babies, of mothers that have used amisulpride 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**

Amisulpride Mylan may make you feel less alert, drowsy or sleepy while taking this medicine. If this happens do not drive or operate machinery until you are sure that you are not affected.

### **Amisulpride Mylan contains lactose**

Amisulpride Mylan 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 Mylan**

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:

Doses are adjusted individually and can range from 50 mg up to 800 mg daily. Your doctor may start you on a lower dose if necessary. If necessary your doctor can prescribe up to 1200 mg each day. This will depend on the nature of your illness and you should follow your doctor's instructions carefully.

If you are taking up to 400 mg Amisulpride Mylan a day, you should take it in one dose. Take the dose at the same time each day. If you are taking more than 400 mg Amisulpride Mylan a day, you should divide the dose into two and take 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 and adolescents (under 18 years of age):

Amisulpride Mylan should not be given to children under 18 years old.

Amisulpride Mylan tablets can be administered independently from the meals. Take this medicine by mouth. Tablets should be taken whole or halved with a sufficient amount of liquid. Do not chew your tablets.

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

Contact your doctor or the hospital immediately. Take this 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 Mylan**

Do not take a double dose to make up for a forgotten dose. Take your next dose at the usual time.

**If you stop taking Amisulpride Mylan**

Do not stop taking Amisulpride Mylan without consulting your doctor. Stopping treatment suddenly may cause withdrawal effects such as feeling sick, vomiting, sweating, sleeplessness, extreme restlessness, muscle stiffness or abnormal movements, or your original condition may come back.

**Blood Tests**

Taking Amisulpride Mylan 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 that you are taking Amisulpride Mylan.

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.

**If any of the following happen, stop taking Amisulpride Mylan and tell your doctor or go to your nearest hospital emergency department immediately:**

*Frequency not known (cannot be estimated from the available data):*

- your heart starts beating faster than usual which could result in heart attack or life-threatening heart disorder.
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- you have high temperature, muscle stiffness, feeling faint or light-headed, confused, drowsy or agitated, paleness, racing heart, fast breathing, changes to blood pressure, sweating, urinary incontinence (these are symptoms of a very rare syndrome called Neuroleptic Malignant Syndrome).
- you have blood clots in the veins specially 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.
- 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 (neutropenia, leucopenia).

*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)

**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, head, neck, jaw or eyes.  
(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 or tongue

**Other side effects include:**

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

- difficulty sleeping (insomnia, drowsiness) or feeling anxious or agitated
- constipation, feeling or being sick, dry mouth
- weight gain
- difficulty reaching orgasm, impotence\*
- unusual secretion of milk from the breasts in women and men, breast pain\*
- breast enlargement in men\*
- menstrual period stops\*
- low blood pressure (causing dizziness)
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- feeling dizzy (which can be due to low blood pressure)

*Uncommon side effects (may affect up to 1 in 100 people):*

- high blood sugar levels (hyperglycaemia)
- elevated liver enzymes
- slowing of the heartbeat

\*These side effects disappear gradually after you stop taking Amisulpride Mylan.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible 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:

### **Ireland**

Pharmacovigilance Section  
Irish Medicines Board

Kevin O'Malley House  
Earlsfort Centre  
Earlsfort Terrace  
IRL - Dublin 2  
Tel: +353 1 6764971  
Fax: +353 1 6767836  
Website: [www.imb.ie](http://www.imb.ie)  
e-mail: [imbpharmacovigilance@imb.ie](mailto:imbpharmacovigilance@imb.ie)

By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Amisulpride Mylan**

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

This medicine does not require any special storage conditions.

Do not use Amisulpride Mylan after the expiry date which is stated on the blister and carton after EXP. The expiry date refers to the last day of that month.

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 Mylan contains**

- The active substance is amisulpride.  
Each Amisulpride Mylan 400 mg film-coated tablet contains 400 mg amisulpride.
- The other ingredients are:  
**Core**  
Lactose monohydrate, methylcellulose, sodium starch glycolate (type A), cellulose, microcrystalline, magnesium stearate.  
**Film coating**  
Basic butylated methacrylate copolymer, titanium dioxide, talc, magnesium stearate, macrogol 6000.

### **What Amisulpride Mylan looks like and contents of the pack**

Amisulpride Mylan 400 mg are white to off white, 18 x 8 mm capsule shaped, film coated tablet with break line on one side in PVC/Aluminium blister packs of 30, 60 or 100 film-coated tablets.

The tablets can be divided into equal doses.

Not all pack sizes may be marketed.

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

McDermott Laboratories Ltd. t/a Gerard Laboratories, Baldoyle, Dublin 13, Ireland.

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

Czech Republic	Amisulprid Mylan 400 mg
Belgium	AmisuMylan
Bulgaria	Amisulgen 400 film-coated tablets
Ireland	Amisulpride Mylan 400mg film-coated tablets

Greece	Amisulpride/Generics film-coated tablets 400 mg
Hungary	Amisulprid Mylan
Italy	Amisulpride Mylan Generics 400mg compresse
Portugal	Amissulprida Mylan
Slovakia	Amisulprid Mylan 400 mg
Slovenia	Amisulprid Mylan 400 mg filmsko obložene tablete
Spain	Amisulprida Mylan Pharmaceuticals

**This leaflet was last approved in 09/2013.**