

## **PACKAGE LEAFLET: INFORMATION FOR THE USER**

AMISULPRIDE MYLAN 50 mg, 100 mg and 200 mg 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. 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 gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

### **In this leaflet:**

1. What Amisulpride Mylan is and what it is used for
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## **1. WHAT AMISULPRIDE MYLAN IS AND WHAT IT IS USED FOR**

Amisulpride Mylan contains a medicine called amisulpride. 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 This condition causes symptoms such as becoming withdrawn, sensing, seeing or hearing things which do not exist, mistaken beliefs or unfounded suspicions.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. BEFORE YOU TAKE AMISULPRIDE MYLAN**

### **Do not take Amisulpride Mylan if you:**

- are allergic (hypersensitive) to amisulpride or any of the other ingredients of Amisulpride Mylan.
- have a prolactin dependent tumour or breast cancer.
- have phaeochromocytoma (a tumour on the adrenal gland).
- are breast-feeding.
- take medicines which could change your heart rate or may affect the amount of Amisulpride Mylan in your blood. Examples of such medicines are:
  - medicines used in the treatment of irregular heart beats (e.g. quinidine, amiodarone, sotalol, dysopyramide or bepridil)
  - antipsychotic drugs (e.g. thioridazine, sultopride)
  - antibiotics (e.g. erythromycin, sparfloxacin or pentamidine)
  - medicines such as vincamine (increase blood flow into brain), cisapride (used to treat stomach problems), halofantrine (used as malaria treatment), methadone (drug addiction treatment)
  - levodopa (used to treat Parkinson's disease)
- have severe kidney disease.

Amisulpride Mylan should not be given to children up to 15 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 Mylan.

### **Take special care with Amisulpride Mylan**

Check with your doctor or pharmacist before taking your medicine if you:

- are an elderly patient
- or someone else in your family has a history of blood clots, as medicines like these have been associated with formation of blood clots.
- have liver disease
- have Parkinson's disease (taking this medicine may worsen your condition)
- have a history of epileptic seizures
- have an abnormal heart rate or rhythm
- 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.

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

### **Taking other medicines**

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Amisulpride Mylan can interact with the following medicines:

- Central Nervous System depressants (drugs which act on the brain), such as pimozide, haloperidol, imipramine and lithium, including narcotics (used for relieving severe pain)
- Anaesthetics
- Sedative H<sub>1</sub> antihistamines (which cause drowsiness)
- Barbiturates and benzodiazepines (sleeping tablets)
- Medicines used to treat high blood pressure and migraine such as clonidine and its derivatives, diltiazem and verapamil, guanfacine and digitalis
- Diuretics, laxatives, glucocorticoids, certain antibiotics which can lower potassium level in your blood.

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

### **Taking Amisulpride Mylan with food and drink**

Do not drink alcohol while you are taking Amisulpride Mylan.

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

Ask your doctor or pharmacist for advice before taking any 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 affect your reactions so you should not drive or operate machinery until you are sure that you are not affected.

### **Important information about some of the ingredients of Amisulpride Mylan**

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 Amisulpride Mylan exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Doses are adjusted individually and can range from 50 mg up to 800 mg daily. This will depend on the nature of your illness and you should follow your doctor's instructions carefully.

If you are taking up to 300 mg Amisulpride Mylan a day, you should take it in one dose. If you are taking more than 300 mg Amisulpride Mylan a day, you should divide the dose into two and take half in the morning and half in the evening.

Amisulpride Mylan tablets can be administered independently from the meals. Tablets should be taken whole or halved with a sufficient amount of liquid.

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

Contact your doctor or the hospital immediately.

#### **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.

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

## **4. POSSIBLE SIDE EFFECTS**

Like all medicines, Amisulpride Mylan 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:**

- your heart starts beating faster than usual
- you have allergic reaction (swelling of skin, tongue, lips, or face, or have difficulties breathing or swallowing)
- you have high temperature, muscle stiffness, feeling faint or light-headed, paleness, racing heart, changes to blood pressure, sweating, urinary incontinence (these are symptoms of a very rare syndrome called Neuroleptic Malignant Syndrome).

**Very common side effects** (affecting more than 1 in 10 people):

- trembling, pronounced muscle stiffness or spasm, slowness of movement, excess saliva or restlessness can occur but this will usually be reduced if your doctor lowers your dose of Amisulpride Mylan or if your doctor prescribes you an additional medicine.

**Common side effects** (affecting fewer than 1 in 10 people):

- insomnia, drowsiness
- anxiety, agitation
- constipation, feeling or being sick, dry mouth, vomiting
- weight gain
- difficulty reaching orgasm, impotence\*
- secretion of milk from the breasts in women, breast pain\*
- breast enlargement in men\*
- temporary stopping of the menstrual periods\*
- low blood pressure (causing dizziness)
- abnormal movements of some eye muscles, intense contraction of the jaws, involuntary twisting of the neck

**Uncommon side effects** (affecting fewer than 1 in 100 people):

- uncontrollable movements, mainly of the face or tongue
- convulsions (fits)
- high blood sugar levels (hyperglycaemia)
- elevated liver enzymes
- allergic reactions
- slowing of the heartbeat

**Frequency of side effects cannot be estimated from available data:**

(postmarketing surveillance):

- sudden death
- stopping of the heart (cardiac arrest)
- dangerous irregular heart rates (ventricular arrhythmias)
- 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.
- 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.

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

**If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.**

## 5. HOW TO STORE AMISULPRIDE MYLAN

Keep out of the reach and sight 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.

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 Mylan contains

- The active substance is amisulpride.  
Each Amisulpride Mylan 50 mg tablet contains 50 mg amisulpride.  
Each Amisulpride Mylan 100 mg tablet contains 100 mg amisulpride.  
Each Amisulpride Mylan 200 mg tablet contains 200 mg amisulpride.
- The other ingredients are: lactose monohydrate, methylcellulose, sodium starch glycolate (type A), cellulose, microcrystalline, magnesium stearate.

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

Amisulpride Mylan 50 mg are white to off-white 6.0 mm round, bi-convex tablets with break line on one side in PVC/Aluminium blister packs of 10, 12, 20, 30, 60 or 90 tablets.

Amisulpride Mylan 100 mg are white to off-white 8.0 mm round, flat tablets with break line on one side in PVC/Aluminium blister packs of 10, 30 or 60 tablets.

Amisulpride Mylan 200 mg are white to off-white 11.0 mm round, flat tablets with break line on one side in PVC/Aluminium blister packs of 10, 30, 60, 90, 120 or 150 tablets.  
The tablets can be divided into equal halves.

Not all pack sizes may be marketed.

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

To be completed nationally.

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

Czech Republic	Amisulprid Mylan 50/100/200 mg
Austria	Amisulprid Arcana 50/100/200 mg - Tabletten
Belgium	AmisuMylan
Bulgaria	Amisulgen 50/100/200 tablets
Ireland	Sulride 50/100/200 mg tablets (the name will be discussed in the national phase)
Greece	Amisulpride/Generics tablets 100 mg
Hungary	Amisulprid Mylan
Italy	Amisulpride Mylan Generics 50/100/200 mg compresse
Portugal	Amisulprida Mylan
Slovakia	Amisulprid Mylan 100/200 mg
Slovenia	Amisulprid Mylan 100/200 mg tablete
Spain	Misulmylan 100/200 mg comprimidos EFG

**This leaflet was last approved in {MM/YYYY}.**

To be completed nationally