

**PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS'  
REGULATIONS (PREPARATIONS) - 1986**

This medicine can be sold with a doctor's prescription only

## **Lormyx 200 mg Film-coated tablets**

### **Ingredients:**

#### **Active ingredient:**

Rifaximin (polymorphic form  $\alpha$ ) 200 mg

For list of excipients - see "Additional Information" section.

**Read this entire leaflet carefully before you start taking this medicine.** This leaflet contains concise information about the medicine. If you have any further questions, ask your doctor or pharmacist.

This medicine has been prescribed for your illness. Do not pass it on to others. It may harm them, even if you think that their illness is the same as yours.

**Lormyx** is intended for use in adults and adolescents over 12 years of age.

**Lormyx** is a broad-spectrum antibiotics of the Rifamycin family. The active ingredient **Rifaximin (polymorphic form  $\alpha$ )** inhibits an enzyme named RNA-polymerase which is found in bacteria and thus affects metabolic processes in bacteria.

**Lormyx** is active mainly in the digestive system.

### **What is the medicine used for?**

**Lormyx** is used for the treatment of digestive system infections caused by bacteria sensitive to the medicine:

- Traveller's diarrhea (TD)
- Damage to the function of the brain due to a chronic liver disease that causes the liver to become incapable of removing toxic substances from the blood, and therefore they reach the brain (Hepatic Encephalopathy)
- Non-complicated diverticular disease (pouches of the colon)

### **Before you take the medicine:**

<b>Do not use the medicine if:</b>
<ul style="list-style-type: none"><li>• You are hypersensitive (allergic) to the active ingredient <b>Rifaximin (polymorphic form <math>\alpha</math>)</b>, other derivatives of the Rifamycin family or to any of the other ingredients of this medicine (please see "Additional Information").</li></ul>



### **Special warnings about the use of this medicine:**

- If your symptoms do not improve within 24-48 hours, refer to your doctor who will consider whether to change your treatment to another medicine.
- Do not use **Lormyx** for the treatment of diarrhea which is accompanied by fever or bloody stool.

- Your urine may be reddish in the following cases:
  - If you are treated with high dosages of the medicine for a long period of time
  - If you suffer from damage to the intestinal tissue
 In these situations small amounts of the medicine (less than 0.4%) can be absorbed into the blood stream and leave the body through the urine. The color of the active ingredient of this medicine is red-orange, the same as all other antibiotics of the Rifamycin family, and this may cause the urine's discoloration.

**Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines**, including non-prescription drugs and nutrition supplements.

Especially inform your doctor or pharmacist if you are taking:

- Oral Contraceptive pills – their effectiveness may decrease, and therefore it is recommended to use additional contraceptives which are not based on hormones taken orally.
- Charcoal – **Lormyx** should be taken at least two hours after taking medicines containing charcoal.

#### **Use of Lormyx with food:**

**Lormyx** can be taken with or without food.

#### **Pregnancy and breastfeeding:**

The medicine should not be used during pregnancy and breastfeeding, since there is no sufficient information regarding the safety of using **Lormyx** during pregnancy and breastfeeding.

#### **Driving and use of machinery:**

There is no expected effect on driving or operating machinery. In rare cases, side effects that may influence the ability to drive or operate machinery may occur.

#### **How to use this medicine**

Always use according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure.

**The dosage and administration will be determined by the doctor only. The usual recommended dosage is:**

- Adults and adolescents over 12 years of age:
  - Traveller's diarrhea: 1-2 film-coated tablets 2-3 times a day (a total of 400-1200 mg a day)
  - Non-complicated diverticular disease (pouches of the colon), damage to the function of the brain due to a chronic liver disease: 2 film-coated tablets 2-3 times a day (a total of 800-1200 mg a day) for each treatment cycle.
- Do not chew the tablets since they are film-coated.
- Swallow with a sufficient amount of fluids (such as a glass of water).
- If you take 2 tablets a day, take one in the morning and one in the evening. If you take 3 tablets a day, take them in the morning, noon and evening.
- Duration of the treatment:
  - Traveller's diarrhea: up to 3 days, unless instructed otherwise by your doctor.
  - Non-complicated diverticular disease (pouches of the colon), damage to the function of the brain due to a chronic liver disease: up to 7-10 days for a single treatment cycle.
 For acute treatment, one treatment cycle is sufficient.

For chronic treatment, one treatment cycle per month.

**If you have accidentally taken a higher dosage** or if a child has accidentally swallowed the medicine, proceed immediately to a doctor or a hospital emergency room and bring the package of the medicine with you. In cases of overdose, gastric lavage (stomach pumping) and an appropriate supporting treatment are recommended.

**If you forget to take this medicine** at the specified time, immediately take the forgotten dose and do not take a double dose at the next time. You should make sure to take the medicine at the appropriate times in order to maintain the treatment's safety and efficacy. Continue with the treatment as recommended by your doctor.

Even if there is an improvement in your health, do not stop taking this medicine or change the dosage without consulting your doctor or pharmacist.

**If you stop taking this medicine**, you may harm the efficacy of the treatment.

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

### **Side effects:**

Like all medicines, **Lormyx** 200 mg can cause side effects, although not everybody gets them. Do not be alarmed while reading the list of side effects, you may not suffer from any of them.

#### **Appear very commonly (effects that appear in more than one user out of ten):**

- Accumulation of gas in the stomach.

#### **Appear commonly (effects that appear in 1-10 users out of 100):**

- Headaches, dizziness, nausea, an urge to defecate, redness of the skin, tingling skin rash (mostly a sign of oversensitivity).

#### **Appear uncommonly (effects that appear in 1-10 users out of 1,000):**

- Stomach aches, tiredness, urgency to urinate, loss of appetite, menstrual disturbances and loss of weight.

#### **Appear rarely (effects that appear in 1-10 users out of 10,000):**

- Increase in values of blood tests that indicate liver function, increase in the level of a protein named aspartate aminotransferase.

#### **Appear very rarely (effects that appear in less than one user out of 10,000):**

- Infectious diarrhea, upper respiratory tract infections, increase of white blood cell count, decrease in blood cells of the neutrophil type, nightmares, migraines, insomnia, ear aches, ringing in the ears, diarrhea, dryness of the throat and lips, inguinal hernia, gum problems, biliary excretion in the urine, pain while urinating, blood in urine, frequent urination, proteins in urine, sunburns.

If you experience a side effect, if any of these side effects worsens, or if you experience side effects not mentioned in this leaflet, consult your doctor.

### **How to store the medicine**

- Avoid poisoning! This medicine, and all other medicines, must be stored in a safe place out of the reach of children and/or infants, to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by your doctor.
- Do not take medicines in the dark! Check the label and the dose each time you take your medicine. Wear glasses if you need them.
- Do not use the medicine after the expiry date (exp. date) stated on the package. The expiry date refers to the last day of that month.
- Do not store at temperature above 30°C.

### **Additional information**

- **In addition to the active ingredient *Rifaximin (polymorphic form α)*, this medicine also contains:**  
Sodium Starch Glycolate, Glycerol Distearate, Anhydrous Colloidal Silica, Talc, Microcrystalline Cellulose, Hypromellose, Titanium Dioxide, Disodium Edetate, Propylene Glycol, Red Iron Oxide E172.
- **What the medicine looks like and contents of the pack:** concave pink film-coated tablets. Marketed in packages of 12 and 24 tablets.
- **Registration holder:** Megapharm Ltd., P.O.B. 519, Hod Hasharon 4510501
- **Manufacturer:** Alfa Wassermann S.p.A, Pescara, Italy
- This leaflet was checked and approved by the Ministry of Health in December 2014.
- **Drug registration number at the national medicines registry of the Ministry of Health:** 149 55 33667

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