PATIENT PACKAGE INSERT IN ACCORDANCE
WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986
This medicine is dispensed with a physician's prescription only

Lormyx 200 mg
Film-coated tablets

Active ingredient:
Each film-coated tablet contains:
Rifaximin (polymorphic form α) 200 mg

For a list of inactive and allergenic ingredients, see Section 6 - "Additional information".

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, consult your physician or pharmacist.
This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them even if it seems to you that their illness is similar.

1. What is this medicine intended for?

Lormyx 200 mg is used for treating infections of the gastrointestinal tract caused by bacteria sensitive to the medicine:

- Traveller's diarrhoea - TD
- Brain damage due to chronic liver disease allowing toxic substances to reach the brain as a result of inability of the liver to remove them from the bloodstream (hepatic encephalopathy)
- Non-complicated diverticular diseases (eversion of the intestinal wall)

Therapeutic group: An antibiotic used for treating gastrointestinal infections.

Lormyx 200 mg is a broad spectrum antibiotic belonging to the rifamycin group. The active ingredient, rifaximin (polymorphic form α), affects bacterial metabolism by inhibiting a bacterial enzyme called RNA-polymerase.
Lormyx 200 mg acts mainly in the gastrointestinal tract.

2. Before using the medicine

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient, rifaximin (polymorphic form α), other derivatives of the rifamycin group or to any of the additional ingredients that the medicine contains (please see Section 6 "Additional information").
- If you are suffering from partial or complete intestinal blockage (ileus).

Special warnings regarding use of the medicine
Before taking Lormyx 200 mg, tell your physician if:

- If you have to be treated with high dosages for a long period of time
- You suffer from an injured intestinal mucosa.

In these cases, small amounts of the medicine (less than 0.4%) may be absorbed into the bloodstream and excreted from the body via the urinary tract.
The colour of the medicine's active ingredient is orange-red, as with most antibiotics in the rifamycin group, and therefore urine is likely to have a reddish colour.
If there is no improvement in symptoms within 24-48 hours, you should stop treatment and see your physician, who will decide whether to replace the medicine with a different one.

Do not use **Lormyx 200 mg** for treating complicated diarrhoea accompanied by fever or bloody stools.

As with other antibiotics, use of this medicine may cause diarrhoea as a result of intestinal infection associated with the Clostridium difficile bacterium ***(Clostridium difficile associated diarrhoea*, CDAD).** Stop treatment and tell your physician immediately if you develop severe or prolonged diarrhoea during or after use of the medicine.

Children and adolescents:
Lormyx 200 mg is intended for use in adults and adolescents older than 12 years of age.

Drug interactions:
If you are taking or have recently taken any other medicines, including nonprescription medicines or nutritional supplements, tell your physician or pharmacist. Particularly if you are taking:

- Cyclosporine (a medicine which suppresses the immune system given to prevent rejection of organ transplants), because concomitant use may lead to increased exposure to ***rifaximin***.

- Activated charcoal (for treating gas, stomach distension) **- Lormyx 200 mg** should be taken at least two hours after taking medicines containing charcoal.

  Since the absorption of **Lormyx 200 mg** by the gastrointestinal tract is negligible (less than 0.4%), the incidence of systemic interactions with other medicines is low. Interactions with drugs that are metabolized the same way cannot be excluded in patients with hepatic impairment (e.g., warfarin [anticoagulant], antiepileptics, antiarrhythmics, oral contraceptives).

Use of the medicine and food
Lormyx 200 mg may be taken with or without food.

Pregnancy, breastfeeding and fertility:
If you are pregnant or breastfeeding, think that you may be pregnant or are planning to get pregnant, consult your physician before taking **Lormyx 200 mg**.

Pregnancy
Taking this medicine during pregnancy is not recommended.

Breastfeeding
A risk to the breast-fed child cannot be excluded.
It is therefore necessary to weigh the potential risk to the breast-fed child against the benefit to the mother, when considering whether to discontinue breastfeeding or discontinue treatment with **Lormyx 200 mg**.

Driving and using machines
The effect of **Lormyx 200 mg** on driving and the ability to operate machines is negligible.
If you feel dizzy or drowsy you should not drive or use machines.

Important information about some of the medicine's ingredients
The medicine contains less than 1 mmol sodium (23 mg) per tablet, and may thus be regarded as *"sodium free".*

3. How should you use the medicine?
Always use this preparation according to your physician's instructions. If you are not sure about the dosage or treatment regimen of the preparation, check with your physician or pharmacist.
The dosage and treatment regimen will be determined by your physician only. The usual dosage is generally:
Adults and adolescents older than 12 years:
- Traveller's diarrhoea: 1-2 film-coated tablets, 2-3 times a day (total of 400-1200 mg per day)
- Non-complicated diverticular diseases, hepatic encephalopathy (brain damage as a result of chronic liver disease):
  2 film-coated tablets, 2-3 times a day (total of 800-1200 mg per day) for each treatment cycle.

Children:
The safety and efficacy of **Lormyx 200 mg** in children younger than 12 years of age has not been established, therefore no recommendation can be given as to treatment regimen.

- Do not chew the tablets, as they are film-coated.
- Swallow with a sufficient quantity of liquid (e.g., a glass of water).
- If 2 tablets a day are being taken, take one in the morning and one in the evening. If 3 tablets a day are being taken, take one in the morning, one in the early afternoon and one in the evening.
- Treatment duration:
  - Traveller's diarrhoea: Should not exceed 3 days, unless otherwise instructed by your physician.
  - Non-complicated diverticular diseases, hepatic encephalopathy (brain damage as a result of chronic liver disease):
    Should not exceed 7-10 days for a given treatment cycle.
    For acute treatment, a single treatment cycle is sufficient.
    For chronic treatment, one treatment cycle per month.

Patients with hepatic or renal insufficiency
No dosage adjustment is necessary for patients with hepatic or renal insufficiency.

Do not exceed the recommended dose.

If you accidentally took a higher dosage or if a child has accidentally swallowed the medicine, proceed immediately to a physician or a hospital emergency room and bring the package of the medicine with you. In cases of overdose it is recommended to perform gastric lavage and provide appropriate supportive measures.

If you forgot to take the medicine at the required time, do not take a double dose. Take the next dose at the regular time and consult your physician.

Make sure to take the medicine at the appropriate times in order to ensure treatment safety and efficacy.
Adhere to the treatment regimen as recommended by your physician.

Even if there is an improvement in your health, do not stop treatment with this medicine or change the dosage without consulting your physician or pharmacist.
If you stop taking the medicine before completion of treatment, you might compromise the efficacy of the treatment.

Do not take medicines in the dark! Check the label and the dose <u>every time</u> you take a medicine. Wear glasses if you need them.

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

4. <u>Side effects</u>

As with any medicine, the use of **Lormyx 200 mg** may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Side effects occurring during treatment with **Lormyx 200 mg** are mainly slight to moderately strong and subside by themselves in the majority of cases, without modification of the dosage or stopping treatment with the medicine.

The following side effects have been reported. The list includes side effects which can also be symptoms of the underlying disease:

<u>Common side effects - effects that may occur in 1-10 users in 100:</u>
Headache, dizziness, abdominal pain, constipation, urge to defecate, diarrhoea, flatulence, abdominal bloating, nausea, vomiting, painful defecation, fever

<u>Uncommon side effects - effects that may occur in 1-10 users in 1,000:</u>
Thrush, herpes simplex (herpes virus), nasal pharyngitis, sore throat, infections of the upper respiratory tract, increase in blood counts of lymphocytes (lymphocytosis) or monocytes (monocytosis), decrease in blood neutrophil cells (neutropenia), reduced appetite, dehydration, bad dreams, depression, sleeplessness, nervousness, decreased skin sensation, migraine, drowsiness, lack of sensation in the limbs, sinusitis headache, double vision, earache, vertigo (spinning dizziness), heart palpitations, increased blood pressure, flushing, cough, dry throat, difficulty breathing, stuffy or runny nose, pain in the mouth and throat, epigastric discomfort, dry lips, indigestion, altered sense of taste, intestinal motility disorders, hard stools, black coloured stools, mucous stools, increased blood levels of aspartate aminotransferase (a liver enzyme which is an indicator of liver function), rash, exanthema, sunburn, back pain, muscle spasms, muscle weakness, muscle pain, neck pain, blood, glucose or proteins in the urine, frequent urinary urgency, increasing urine output, menstrual irregularity, asthenia (weakness, fatigue, lack of energy), chills, cold sweats, profuse sweating, flu-like symptoms, fluid retention in the arms and legs, pain and discomfort

<u>Side effects of unknown frequency (of which frequency has not yet been determined):</u>
Bacterial infection (Clostridia), decreased blood platelet counts, anaphylactic shock (severe life threatening allergic reaction which causes breathing difficulty and a drop in blood pressure to dangerously low levels), hypersensitivity, fainting or a feeling of impending fainting, changes in *INR*

values (a blood clotting indicator), liver function test abnormalities, allergy, painful swelling of skin and mucosal tissues mostly in the facial area, skin inflammation, peeling of the skin, eczema, skin redness, itching, bruising, urticaria (hives).

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in this leaflet, consult your physician.

Reporting of side effects:
Side effects can be reported to the Ministry of Health by clicking on the link "Report on Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: https://sideeffects.health.gov.il.

5. How should the medicine be stored?

- Avoid poisoning! This medicine, and any other medicine, should be kept in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by your physician.
- Do not use this medicine after the expiry date (exp. date) which appears on the carton. The expiry date refers to the last day of that month.

Storage conditions:

- Store at a temperature below 30°C.
- Do not throw away medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines that you no longer use. These measures will help protect the environment.

6. Additional information

- In addition to the active ingredient Rifaximin (polymorphic form α), the medicine also contains:
  Microcrystalline Cellulose, Glycerol Distearate, Sodium Starch Glycolate, Anhydrous colloidal silica, Talc

  The tablet's film coating contains:

  Hypromellose, Titanium Dioxide, Propylene Glycol, Red Iron oxide E172, Disodium Edetate

  What the medicine looks like and what the package contains:

  Pink-coloured, biconvex film-coated tablets. Available in packages of 12, 24 and 36 tablets.

  Not all package sizes may be available.

- **Registration holder and address:** Megapharm Ltd., P.O.B. 519,

  Hod Hasharon 4510501, Israel.

- **Manufacturer and address:** Alfasigma S.P.A., Alanno, Italy.
- **Revised in December 2021 according to Ministry of Health guidelines.**
- **Registration number of the medicine in the National Drug Registry of the Ministry of Health:** 149-55-33667.