

PACKAGE LEAFLET: INFORMATION FOR THE USER

Linex

Hard capsules

LACTOBACILLUS ACIDOPHILUS (LA-5) BIFIDOBACTERIUM ANIMALIS SUBSP. LACTIS (BB-12)

• *This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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 •*

What is in this leaflet?

1. What LINEX is and what it is used for
2. Before you take LINEX
3. How to take use LINEX
4. Possible side effects
5. How to store LINEX
6. Further information

1. WHAT LINEX IS AND WHAT IT IS USED FOR

LINEX is a probiotic, which contains three species of viable lyophilised lactic acid bacteria which regulate the physiological balance of the intestinal microflora.

Lactic acid bacteria are normally present in the small and large intestine where they keep the acid-alkaline balance needed for the normal functioning of digestive enzymes, immune system and bowel habit (peristalsis). When the amount of lactic acid bacteria is inadequate the balance of endogenous intestinal bacterial flora is destroyed, resulting in various digestive disorders.

Lactic acid bacteria in Linex are lyophilised (i.e., dried out under low temperature). This allows the storage of the medicine at room temperature without any effect on the form or activity of bacteria.

Linex is used as preventive and as supportive treatment in diarrhea, meteorism and other digestive disorders resulting from microflora imbalance. This can occur at:

- viral and bacterial gastrointestinal infections in infants, children and adults (e.g., rotavirus infection, traveller's diarrhea)
- treatment with a broad-spectrum antibiotics and chemotherapeutics
- irradiation of abdominal and pelvic organs

Use of probiotic or lactic acid bacteria efficiently lowers the frequency and potency of mild to moderate digestive disorders due to imbalance of intestinal microflora.

2. BEFORE YOU TAKE LINEX

Do not take LINEX

If you are hypersensitive (allergic) to any of the active ingredients, or any of the other ingredients of Linex

Take special care with LINEX

- you have body temperature above 38 °C
- you noticed blood or mucus in your stool
- diarrhea lasts more than two days
- you have intense diarrhea accompanied with dehydration and body weight loss
- severe abdominal pain accompanied your diarrhea
- you have other chronic diseases (e.g diabetes, cardio-vascular diseases) or immunodeficient (e.g. HIV infection).

Diarrhea in infants and children younger than six years should be treated only under the doctor supervision.

In self-treatment of diarrhea, it is the first and the most important action to substitute the loss of liquid and electrolytes.

Taking other medicines

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

No clinically significant interaction with other medicinal products has been done so far. In laboratory studies the natural resistance to certain antibiotics and chemotherapeutics has been determined.

Linex capsules could be taken along with antibiotics and chemotherapeutics, preferably not at the same time. For better efficacy of the medicine, it is recommended to take capsules Linex at least 3 hours after taking antibiotics or chemotherapeutics.

Taking Linex together with food and drink

You should take Linex during meals to avoid harmful effect of stomach juice on lactic acid bacteria. You should not take Linex concomitantly with alcohol or hot beverages.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Treatment of diarrhea during pregnancy and breastfeeding should be under medical supervision.

Self-treatment of diarrhea during pregnancy and breast feeding is not recommended. Since there are not enough data or experience in the use of Linex during pregnancy and breast-feeding, we do not recommend its use in these conditions.

Driving and using machines

No available data on influence of medicine on the ability to drive and use machines.

Important information about some ingredients of LINEX

Linex contains glucose, fructose and saccharose. If your doctor told you have an intolerance to some sugars, contact your doctor before taking this medicine.

LINEX may contain traces of milk proteins that can cause allergic reaction (hypersensitivity reaction).

3. HOW TO TAKE LINEX

Always take LINEX exactly as indicated in this package leaflet. If you are unsure, please ask your doctor or pharmacist for advice.

- Linex should be used orally (through the mouth)
- You should take Linex at meals to avoid harmful effect of stomach juice on lactic acid bacteria
- You should not take Linex concomitantly with alcohol or hot beverages
- For a child who is not able to or does not know how to swallow the capsules, open the capsule shell, empty the contents onto a spoon and mix it with some liquid.

The usual dose and duration of treatment:

- Infants and children up to 2 years: 1 capsule three times daily (in the morning and in the evening)
- Children aged 2 to 12 years: 1-2 capsules three times daily (in the morning and in the evening)
- Adults and children over 12 years of age: 2 capsules three times daily (in the morning and in the evening)

You can take LINEX as long as symptoms persist. In case of diarrhea that lasts more than two days, you should contact a doctor.

In self-treatment of diarrhea, it is the first and the most important action to substitute the loss of liquid and electrolytes.

If you take more LINEX than you should

No symptoms of overdose or poisoning are known for LINEX.

If you forget to take LINEX

If you take too few LINEX capsules or forget to take a dose, do not take a double dose next time, but continue taking the medicine as prescribed by your doctor or as indicated in the package leaflet.

Talk to your doctor or pharmacist if you have any additional questions.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Side effects after lactic acid bacteria consumption are very rare (less than 1 patient out of 10,000). Reaction or hypersensitivity could occur.

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.

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

5. HOW TO STORE LINEX

Keep out of the reach and sight of children.

This medicine should no longer be used after the expiry date printed on the container. The expiry date is the last day of the month indicated.

Expiration date: 2 years

Storage conditions:

Do not store above 25 °C. Store in the original package in order to protect from moisture.

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 LINEX contains

Each hard capsule contains not less than 1.2 x 10⁷ colony forming units of viable lactic acid bacteria species Lactobacillus acidophilus (sp. L. gasseri), Bifidobacterium infantis, Enterococcus faecium.

The other ingredients: magnesium stearate, lactose, dextrin, potato starch, gelatin, titanium dioxide (E 171).

What LINEX looks like and contents of the pack

White and non-transparent capsule containing white odorless powder.

Box containing 16 hard capsules in aluminium blisters (2 x 8)

Supplier and Manufacturer

Regime of dispensing

The medicine is issued without doctor's prescription.

Manufacturer

Lek farmacevtska družba d.d., Verovškova 57, 1526 Ljubljana, Slovenia

Marketing authorization holder

Novartis BA d.o.o., Antuna Hangija b.b., Sarajevo, Bosna i Hercegovina

Date and number of licenses for the marketing authorization

Linex forte, capsule, hard, 16 capsules in a cardboard box: 04-07.3-2-5378/15 from 02.02.2016.