

## PACKAGE LEAFLET: INFORMATION FOR THE USER

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### Linex Baby

Powder for oral suspension

VIABLE LYOPHILIZED BIFIDOBACTERIUM ANIMALIS SUBSP. LACTIS (BB-12)

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*• 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 •*

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#### What is in this leaflet?

1. What LINEX BABY is and what it is used for
2. Before you take LINEX BABY
3. How to take LINEX BABY
4. Possible side effects
5. How to store LINEX BABY
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#### *1. WHAT LINEX BABY IS AND WHAT IT IS USED FOR*

LINEX BABY contains Bifidobacterium animalis subsp. Lactis that help establish and maintain a balanced and healthy intestinal microflora of infants and children and in the prevention and as adjunctive therapy in the treatment of diarrhea, flatulence and other digestive disorders that result from changes in 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 (normal digestion), immune system and intestinal motility (peristalsis). Additionally, they prevent excessive multiplication of harmful bacteria.

Intestinal microflora of infants primarily contains these bacteria and they are considered important in early childhood.

#### *2. BEFORE YOU TAKE LINEX BABY*

#### **Do not take LINEX BABY**

- If your child is hypersensitive (allergic) to any of the active ingredients, or any of the other ingredients of Linex Baby

### **Take special care with LINEX BABY if the child has**

- body temperature above 38 °C
- blood or mucus in your stool
- diarrhea that lasts more than two days
- intense diarrhea accompanied with dehydration and body weight loss
- severe abdominal pain accompanied your diarrhea
- 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.

For better efficacy of the medicine, it is recommended to take capsules Linex Baby at least 3 hours after taking antibiotics or chemotherapeutics.

### **Taking Linex Baby together with food and drink**

You should give Linex Baby during meals to avoid harmful effect of stomach juice on lactic acid bacteria. You should not give Linex Baby concomitantly with 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.

### **Linex Baby is intended especially for children.**

There are no reported side effects during the application of Linex Baby in pregnant and breastfeeding women.

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

Self-treatment of diarrhea during pregnancy and breast feeding is not recommended.

### **Driving and using machines**

Linex Baby is intended especially for children.

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

Important information about some ingredients of LINEX BABY

Medicine contains maltodextrin which is a mixture of glucose, disaccharides and polysaccharides and is obtained by partial hydrolysis of starch. If you have been told by your doctor that you have intolerance to some sugars, before you start taking this medicine, consult your doctor.

## **3. HOW TO TAKE LINEX BABY**

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

- Linex Baby should be used orally (through the mouth).
- You should give Linex Baby with meals to avoid harmful effect of stomach juice on lactic acid bacteria.
- You should not give Linex Baby concomitantly with hot beverages.

The usual dose and duration of treatment:

**Infants and children up to 2 years:** one bag, once a day.

**Children from 2-12 years:** one bag, one to two times a day (eg, morning and evening).

Pour the contents of the bag into a glass of water, juice or milk. The powder can be mixed with baby food.

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

During the treatment of diarrhea you should recompense for the loss of liquid and electrolytes.

If you take more LINEX BABY than you should

No symptoms of overdose or poisoning are known for LINEX BABY.

### ***If you forget to take LINEX BABY***

If you take too few LINEX BABY 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 BABY***

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:

Do not store above 25 °C. Store in the original package.

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 BABY contains***

The active substance: Live lyophilized bifidobacteria, animal, dairy BB-12, One bag contains at least 1 x 10<sup>9</sup> CFU of live lyophilized bifidobacteria, animal, dairy BB- 12 Bifidobacterium animalis ssp. lactis (BB-12).

The other ingredients: maltodextrin.

### ***What LINEX BABY looks like and contents of the pack***

White to light beige powder for oral suspension.

10 bags containing 1.5 g of powder in a box.

20 bags containing 1.5 g of powder in a box.

***Regime of dispensing***

The medicine is issued without doctor`s prescription.

***Manufacturer***

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