

Package leaflet: information for the user**Lactovaginal**

Vaginal capsules, hard

Lactobacillus rhamnosus 573 rodsabout 10^{10} (not less than 10^8 CFU*)

*CFU – Colony Forming Unit

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your doctor or pharmacist, if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse.

What is in this leaflet

1. What Lactovaginal is and what it is used for
2. What you need to know before you use Lactovaginal
3. How to use Lactovaginal
4. Possible side effects
5. How to store Lactovaginal
6. Contents of the pack and other information

1. What Lactovaginal is and what it is used for

The active substance of Lactovaginal is live lactic acid bacteria of *Lactobacillus rhamnosus* 573 strain.

These bacteria metabolise compounds which are present in vagina environment to such products as lactic acid, maintaining in this way adequate pH of vagina. An acidic vaginal pH (4.0-4.7) inhibits growth of pathogenic bacteria. It has been demonstrated that the use of Lactovaginal medicinal product after vaginal inflammation treatment with antibacterial, trichomonadicidal and antifungal medicines decreases the number of pathogens, restores vaginal natural microbiological balance and normalizes vaginal secretion.

Probiotic preparations with live *Lactobacillus* bacteria are recommended in case of disorders of vaginal flora, which may be caused by treatment with antibiotics therapy, hormonal changes, stress or improper hygiene or sexual habits.

Theapeutic indications

Lactovaginal is recommended for females over 16 years of age to restore or supplement the normal bacterial flora of the vagina. The medicine is recommended:

- in prophylaxis,
- in inflammatory states of genital tract, following the treatment with antibacterial, trichomonadicidal or antifungal medicines,
- in the occurrence of vaginal discharge.

2. What you need to know before you use Lactovaginal**Do not use Lactovaginal**

- if you are allergic to *Lactobacillus* rods or any of the other ingredients of this medicine (listed in section 6), manifested in itching or burning sensations after application of the medicine.

Warning and precautions

Take special care if you suffer from severe immune system disorders. In this case, talk to your doctor before using Lactovaginal.

Other medicines and Lactovaginal

Lactovaginal medicine should not be used in patients receiving antibacterial, trichomonadicidal or antifungal medicines (except for metronidazole and cotrimoxazole) as they may kill *L. rhamnosus* 573 rods or inhibit their growth. *Lactobacillus rhamnosus* 573 was confirmed to be resistant to cotrimoxazole and metronidazole and that Lactovaginal can be used during treatment with these medicines.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other any other medicines.

Pregnancy and breast-feeding

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

Driving and using machines

Using Lactovaginal has no influence or has negligible influence on ability to drive and use machines.

3. How to use Lactovaginal

The usual dose of Lactovaginal is 1 to 2 capsules per day (one in the morning and one at night) for one week. If necessary the treatment should be repeated after checking with the doctor. In case of doubt, check with your doctor or pharmacist again.

The capsule should be inserted deep in the vagina, observing all personal hygiene rules.

If you use more Lactovaginal than you should

Overdose does not pose a threat to a patient.

If you forget to use Lactovaginal

Take your next dose at the normal time. Do not take a double dose to make up for forgotten dose.

If you stop using Lactovaginal

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

4. Possible side effects

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

This medicine is well tolerated. Very rarely, fewer than 1 in 10 000 patients treated possible local side effects like: itching, burning sensations, increase of vaginal secretion occur.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet. You can also report side effects directly via Departament Monitorowania Niepożądanych Działań Produktów Leczniczych Urzędu Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych, Al. Jerozolimskie 181C, 02-222 Warszawa, tel.: +48 22 49 21 301, faks: +48 22 49 21 309, e-mail: ndl@urpl.gov.pl

Adverse reactions can also be reported to the Marketing Authorisation Holder.

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

5. How to store Lactovaginal

Store in a refrigerator (2°C - 8°C). During period of validity medicine may be stored out of refrigerator in temperature up to 25°C for limited period- up to 4 weeks.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the box or blister. The expiry date refers to the last day of that month.

6. Contents of the pack and other information

What Lactovaginal contains

The active substance of Lactovaginal is live lactic acid bacteria of *Lactobacillus rhamnosus* 573 strain, about 10^{10} (not less than 10^8 CFU).

The other ingredients are: skimmed milk powder, saccharose, sodium L- glutamate, potato starch, magnesium stearate, mannitol and capsule ingredients: gelatine and titanium dioxide.

What Lactovaginal looks like and contents of the pack

Lactovaginal capsules are white. They are available in the following pack sizes:

- 1 blister containing 10 capsules, packed in a cardboard box,
- 2 blisters containing 7 capsules, packed in a cardboard box,
- 4 blisters containing 7 capsules, packed in a cardboard box.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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