

LEAFLET: INFORMATION FOR THE USER

Read this leaflet carefully before taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others; It may harm them, even if they have the same symptoms.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What is Normogin and what is it used for
2. Before you use Normogin
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4. Possible side effects
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1. WHAT NORMOGIN WHAT IS IT USED FOR

Normogin contains a culture lyophilisate from a specific strain of Doederlëin Bacillus (*Lactobacillus rhamnosus*). This strain is a constituent of the vaginal flora in healthy women and is the natural defense mechanism against the establishment and proliferation of pathogenic microorganisms. Normogin is used to restore the natural and healthy vaginal flora.

The balance in the vaginal ecosystem can be altered by certain physiological conditions and certain medical treatments. General or local antibiotic or sulfonamide therapy is essential for the treatment of specific types of vaginitis but have a harmful effect in the vaginal flora and exposes the patient to the risk of recurrent vaginitis.

Normogin allows the natural bacterial flora to be re-established: by inserting lactobacilli concentrate deep in the vagina lactobacilli multiply quickly, restoring the optimal value of the vaginal pH and flora. In addition, the habitat created by Normogin is unfavorable for the survival and proliferation of bacteria pathogens. Normogin is a useful aid to restore physiological conditions in the vagina after medical treatment.

Normogin is not effective when using antimicrobials, but it should be used immediately after completing the antimicrobial treatment.

2. BEFORE USING NORMOGIN

Do not use Normogin

If you are hypersensitive to any of Normogin components.

In children under 18 years.

Normogin use with other medicines

Normogin must not be used at the same time as the treatment with antibiotics because antibiotics can inactivate the lactobacillus.

Normogin should be used shortly after the antibiotic treatment.

There are no known interactions with other medications during concomitant therapies.

Pregnancy and lactation

Doederlein bacillus (*Lactobacillus rhamnosus*) is a non-pathogenic bacteria naturally present in the vagina of healthy women so, Normogin can be used during pregnancy and lactation.

Driving and using machines

Normogin has no influence on the ability to drive or operate machinery.

Important information about some of the components of Normogin

Normogin contains lactose monohydrate. If you are hypersensitive to lactose monohydrate you may want to consult your doctor before using Normogin.

3. HOW TO USE NORMOGIN

Normogin is used in the restoration of physiological vaginal flora after vaginal infections and / or after local or systemic treatment with anti-infectives (including antibiotics):

Adults: 1 vaginal tablet 1 or 2 times per day, inserted deep in the vagina.

Normogin should be used right after the treatment with antibiotics for at least 12 days.

Maintaining physiological vaginal flora to prevent the recurrence of vaginal infections:

Adults: 1 or 2 vaginal tablets per day for 6 days followed by 1 per week vaginal tablet to be inserted into the vagina for medium or long term treatment (2 to 24 months).

Normogin can also be used during your menstrual period.

Normogin should not be used at the same time as antibiotic treatment because antibiotics can inactivate lactobacillus.

Normogin should be used shortly immediately after the antibiotic treatment.

Children (under 18 years):

Normogin is not recommended for children under 18 years as the experience in children is limited.

Condom use is not a contraindication of Normogin, however some condoms may contain spermicide substances that can make inactive the lactobacillus. In this case the additional administration of 1 vaginal tablet should be appropriate.

There is no known effect of Normogin on condom effectiveness.

Always use Normogin as prescribed by your doctor. You should consult your doctor or pharmacist if you have questions.

If you use Normogin more than you should

No cases of overdose have been reported and there are no known effects that may be associated with overdose.

If you forget to use Normogin

If you forget to use a dose of Normogin, use the recommended dose as soon as possible. If you miss a dose and it is time for your next use only one dose and continue with the treatment as specified. Do not use a dose to double to make up for the one you forgot.

If you have forgotten several doses, tell your doctor or pharmacist. They may advise you to start a new cycle of treatment.

If you stopped using Normogin

It is highly recommended not to stop the use of Normogin, even if symptoms disappear. If you have questions about the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Normogin can cause side effects.

No serious side effects have been reported. Have been reported rare cases of non-serious side effects such as rash (hives) and slight irritation at the site of application.

If you develop skin irritation or side effects not listed in this leaflet, stop using Normogin and consult your doctor or pharmacist.

5. HOW TO STORE NORMOGIN

Store in a refrigerator (2 ° C - 8 ° C).

It is advisable to return expired medicines to your pharmacist

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

Do not use Normogin after the expiry date mentioned on the pack. The expiration date refers to the last day of the indicated month

6. OTHER INFORMATION

What is the composition of Normogin

The active substance is a lyophilized culture of Doederlein bacillus (Lactobacillus rhamnosus) 40 mg per tablet.

The other ingredients are lactose monohydrate, magnesium stearate.

How does Normogin look like and contents of the pack

Vaginal tablets are white, oblong, and scored on one side.

Each glass bottle contains 6 tablets. The bottle is packed in a cardboard box with an information leaflet.

Marketing Authorization Holder and Manufacturer

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For additional information on this product, please contact the Marketing Authorization Holder.

This leaflet was last approved in