

Package leaflet: information for the patient

inVag

Vaginal capsules, hard

Not less than 10⁹ CFU* of lactic acid bacteria: 25% *Lactobacillus fermentum* 57A,
25% *Lactobacillus plantarum* 57B, 50% *Lactobacillus gasseri* 57C

*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 have told you.

- Keep this leaflet. You may need to read it again.
- Ask your 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 after 7 days.

What is in this leaflet

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

1. WHAT INVAG IS AND WHAT IT IS USED FOR

The active substance of inVag is composed of live lactic acid bacteria: *Lactobacillus fermentum* 57A, *Lactobacillus plantarum* 57B and *Lactobacillus gasseri* 57C.

The medicine is used in woman to restore or supplement normal vaginal flora and to maintain the correct pH in the vagina. The activity of the inVag consists in maintaining the correct microbiological balance within the genitourinary tract and the prevention of infection development.

A clinical study demonstrates that inVag is safe and bacteria which enter into the composition of inVag colonize the vaginal epithelium.

Probiotic products with live *Lactobacillus* bacteria are recommended to use in case of disorders of normal vaginal flora, which may be caused by antibiotic treatment, hormonal changes, stress or improper hygienic and sexual habits.

You must talk to a doctor if you do not feel better or if you feel worse after 7 days.

Therapeutic indications

inVag is used in women to restore or supplement normal vaginal flora and to maintain the correct pH in the vagina.

The medicine is recommended:

- in prevention of genitourinary tract infections:
 - during and after antibiotic treatment and other antibacterial, antitrichomonal and antifungal medicines,
 - during menopause and after puerperium,

- in prophylaxis in all conditions which can lead to disorders of vaginal flora (for example improper hygienic habits, contraception),
- in supportive treatment of vaginal inflammations (vaginal infections), during and after antibiotic treatment, other antibacterial and (or) antifungal medicines (including the treatment of vaginal discharge).

2. WHAT YOU NEED TO KNOW BEFORE YOU USE INVAG

Do not use inVag

- if you are allergic (hypersensitive) to active substance or any of the other ingredients of inVag (listed in section 6).

Warnings and precautions

- take special care with inVag, if you have severe disorder of the immune system. In this case, ask your doctor for advice before using inVag.

Other medicines and inVag

inVag **may be used during** the treatment with norfloxacin, nalidixic acid or metronidazole owing to the resistance of strains contained in inVag to the above- mentioned substances.

Treatment with inVag **may be less effective** during concurrent treatment with sulfamethoxazole and (or) concurrent using spermicidal agents which contain nonoxynol-9.

Treatment with inVag **may be ineffective** during concurrent treatment with penicillin, ampicillin, gentamicin, clindamycin, chloramphenicol and tetracycline because the strains contained in inVag are sensitive to these substances.

Orally taken vitamin B-complex and vaginal treatment with estrogens have beneficial effect on growth of lactobacilli and their colonization (settlement) in the vagina.

Tell your doctor or pharmacist if you are taking or have recently taken or might take 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 taking this medicine.

Driving and using machines

Using inVag has no influence on ability to drive and use machines.

3. HOW TO USE INVAG

Use one capsule every night for 1 week. The capsule should be inserted deep in the vagina, maintaining all rules of personal hygiene. Repeat the therapy if necessary after consulting your doctor. If you have any further questions on the use of inVag, ask your doctor or pharmacist.

inVag use in children

inVag is not recommended for children because of lack of data regarding the safety and efficacy.

If you take more inVag than you should

A higher dose of the medicine does not pose any threat for the patient.

If you forget to use inVag

If you forget to use inVag, use the next dose at the usual time. Do not use a double dose to make up a forgotten dose.

If you stop using inVag

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

4. POSSIBLE SIDE EFFECTS

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

In clinical study carried out on adult women no serious side effects were observed. However, other mild to moderate side effects were observed but they occurred with the same frequency in the control and the inVag group. The side effects were evaluated as unlikely to be or probably related to the use of the medicine.

Common side effects (these may occur in 1 to 10 in 100 patients);

The following common, i.e. in 1 to 10 in 100 patients side effects were reported in clinical study:

- vaginal discharge, pruritus, burning sensation, hypogastric pain, spotting, vulval oedema and reddening, cervix reddening (which was observed by gynecologist),
- frequent passage of urine, urgency
- common cold
- headache

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible 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.: 22 49-21-301, fax: 22 49-21-309, e-mail: ndl@urpl.gov.pl.

Side effects 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 INVAG

Store in a refrigerator (2°C - 8°C).

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

Do not use inVag after the expiry date which is stated on the cardboard box and blister.

The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What inVag contains

The active substance of inVag is composed of live lactic acid bacteria: 25% *Lactobacillus fermentum* 57A, 25% *Lactobacillus plantarum* 57B and 50% *Lactobacillus gasseri* 57C in the amount not less than 10⁹ CFU* per capsule.

CFU*- Colony Forming Unit.

The other ingredients are: skimmed powdered milk, saccharose, sodium L-glutamate, mannitol, lactose monohydrate and magnesium stearate, and capsule ingredients: gelatin and titanium dioxide.

What inVag looks like and contents of the package

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

- 1 blister with 7 capsules in a cardboard box,
- 2 blisters with 7 capsules in a cardboard box,

Not all pack sizes may be marketed.

Marketing Authorization Holder and Manufacturer

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