

GYNOFLOR VAGINAL TABLETS®

Lactobacillus acidophilus/Estriol (100 million viable/0.03mg)

What is in this leaflet

1. What *Gynoflor* is used for
2. How *Gynoflor* works
3. Before you use *Gynoflor*
4. How to use *Gynoflor*
5. While you are using it
6. Side effects
7. Storage and Disposal of *Gynoflor*
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

What *Gynoflor* is used for

Gynoflor is used for restoration of the vaginal lactobacilli flora after treatment with certain medicines (e.g. anti-infective or chemotherapy), treatment of atrophic vaginitis (thinning, drying and inflammation of vaginal walls) due to your body having less estrogen hormone during and after menopause as well as for co-medication to systemic hormone replacement therapy. It is also used for treatment of vaginal discharge of unknown origin or mild to intermediate cases of vaginal infections, where the use of anti-infective or chemotherapy agents is not absolutely necessary. It can be used for preventive treatment of recurrent vaginal infections.

How *Gynoflor* works

Gynoflor contains active substances that are identical to substances found naturally in the human vagina. The healthy vagina is in a state of biological equilibrium and possesses a natural protection mechanism against infections. The lactobacilli bacteria (e.g. *Lactobacillus acidophilus*) constitute a main part of this protection mechanism by producing lactic acid and other substances which have an anti-infective activity. The production of lactic acid results in an acidic environment, favouring the growth of the lactobacilli bacteria but inhibiting the growth of pathogenic micro-organisms. Disturbance or destruction of the vaginal lactobacilli flora can be caused by treatment with certain medicines (e.g. antibiotics), local infections, serious

general illnesses or improper hygienic measures (vaginal rinses and douches). *Gynoflor* contains viable lactobacilli bacteria in a high dose which help to restore the natural flora in the vagina. In addition to a natural flora, a healthy vaginal lining is also important for the natural protection mechanism of the vagina. The vaginal lining can be damaged as a result of fluctuating or deficient hormone levels (in particular during and after menopause) and vaginal infections. *Gynoflor* contains estriol as a second active substance, which is a natural female sex hormone. Estriol, even in the very low dose contained in *Gynoflor*, ensures that the vaginal lining is regenerated, has good blood circulation, is thick enough, elastic as well as moist. This is important also for the growth of the lactobacilli bacteria in the vagina. The lactobacilli bacteria and estriol exert their actions locally within the vagina. Multiplication and re-colonisation of the lactobacilli bacteria begins directly after the first application.

Before you use *Gynoflor*

- When you must not use it

You must not use *Gynoflor* if you have:

- Hypersensitivity to any of the ingredients listed in Product Description
- Estrogen-dependent tumours in the breast, uterus or vagina
- Suspected or confirmed endometriosis (appearance of tissue lining of the uterus outside the womb).
- Vaginal bleeding of unknown origin
- not reached sexual maturity (young girls) should not use this preparation

Pregnancy and lactation

Gynoflor can be used during pregnancy and breastfeeding. Ask your doctor or pharmacist for advice before taking any medicine.

- Before you start use it

Before you use *Gynoflor* tell your healthcare provider if you are taking anti-infective agents.

Taking other medicines

Lactobacillus acidophilus is sensitive to various anti-infective agents. Simultaneous treatment of such agents may lead to a reduction in the efficacy of *Gynoflor*.

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

How to use *Gynoflor*

- How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

Restoration therapy, vaginal discharge of unknown origin, mild to intermediate vaginal infections: 1 – 2 vaginal tablets daily for 6 – 12 days.

Atrophic vaginitis:

A dose of 1 vaginal tablet daily is recommended for 6 – 12 days, followed by a maintenance dose of 1 vaginal tablet at 1 – 2 days per week.

- When to use it

The vaginal tablets should be inserted deeply into the vagina in the evenings before retiring. This is best performed in a reclining position with the legs slightly bent.

Treatment should be interrupted during menstruation and resumed afterwards.

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- How long to use it

If not otherwise instructed by your doctor, follow the directions below.

Restoration therapy, vaginal discharge of unknown origin, mild to intermediate vaginal infections: The therapy takes about 6 – 12 days.

Vaginal complaints during and after menopause co-medication to systemic hormone replacement therapy: therapy is recommended for 6 – 12 days, followed by a maintenance dose as advised by your doctor.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. However, no case of overdose has been reported to date.

While you are using it

- Things you must do

Gynoflor contains excipients which do not dissolve completely, such that remains of the tablet could occasionally be found in the panties. This is of no importance for the efficacy of Gynoflor. In rare cases of a very dry vagina, it is possible that the vaginal tablet does not dissolve and is discharged by the vagina as intact tablet. As consequence, the treatment

is not optimal. However, this is not harmful to the vagina. For prevention, the vaginal tablet can be moistened with a drop of water before insertion into a very dry vagina. You should use a sanitary towel or panty liner.

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Gynoflor.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

You should not use vaginal douches or rinses during treatment with Gynoflor.

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor or pharmacist.

Do not give Gynoflor to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

If Gynoflor is accidentally taken orally; no adverse effects are to be expected.

Side effects

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

The following adverse drug reaction could be observed after the usage of Gynoflor: A mild stinging or burning may be experienced shortly after the insertion of Gynoflor. In rare cases, intolerance reactions such as redness and itching have been reported. An allergy to the *Lactobacillus lyophilisate* contained in Gynoflor was detected.

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.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website npra.moh.gov.my (Public → Reporting Medicinal Problems / Side Effects / AEFI / Vaccine Safety).

Storage and Disposal of Gynoflor

- Storage

Keep out of the reach and sight of children.

Do not use your medicine after the expiry date.

Store in a refrigerator (2 °C – 8 °C). Storage of Gynoflor at room temperature during the 1 – 2 weeks treatment period is possible.

- Disposal

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.

Product Description

- What it looks like

The vaginal tablets are slightly beige, spotted, oval and biconvex.

- Ingredients

- Active ingredients: 100 million viable *Lactobacillus acidophilus*, 0.03 mg Estriol

- Inactive ingredients: Lactose, Disodium phosphate anhydrous, Cellulose microcrystalline, Sodium starch glycolate, Magnesium stearate

- MAL number:

MAL20071631ACZ

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Lactobacillus acidophilus/Estriol (100 million viable/0.03mg)

Manufacturer

Haupt Pharma Amareg GmbH
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Germany

Product Registration Holder

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