

SCHEDULING STATUS

S2

GYNOFLOR vaginal tablets

1 x 10⁸ cfu viable *Lactobacillus acidophilus* / 0,03 mg estriol

Read all of this leaflet carefully because it contains important information for you

GYNOFLOR is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use **GYNOFLOR** carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share **GYNOFLOR** with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 12 days.

What is in this leaflet

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

1. What GYNOFLOR is and what it is used for

What is GYNOFLOR?

GYNOFLOR is a vaginal tablet containing the two active substances, *Lactobacillus acidophilus* and estriol.

What is *Lactobacillus acidophilus*?

Lactobacillus acidophilus is a non-pathogenic bacterium (it does not cause infection), and is a major component of microbiological vaginal flora. It has a positive effect on the vagina because it breaks down glycogen to lactic acid, which lowers the pH in the vagina and the resulting acidic environment prevents the growth of pathogenic bacteria and fungi in the vagina.

What is estriol?

Estriol is a derivative of oestrogen (female hormone) and works by accelerating the maturation of the vaginal epithelium (lining). It also works by accumulating glycogen which is a food for *Lactobacillus acidophilus* bacteria.

What is GYNOFLOR used for?

Atrophic vaginitis, a condition that occurs due to decreased levels of oestrogen in women, usually in postmenopausal women. Because of decreased oestrogen, postmenopausal women are more susceptible to vaginal infections.

2. What you need to know before you use GYNOFLOR

Do not use GYNOFLOR

- if you are hypersensitive (allergic) to *Lactobacillus acidophilus*, estriol or any of the other ingredients of **GYNOFLOR** (listed in section 6);
- if you have breast cancer, suspect that you might have breast cancer or if you have a history of breast cancer;
- if you have an oestrogen-dependent cancer like breast cancer, ovarian cancer and endometrial (uterine) cancer which rely on oestrogen to develop and grow;
- if you have endometriosis, a condition where the layer of tissue that normally covers the

- inside of the womb, grows outside of it;
- if you have an untreated thickening of the lining of the womb;
 - if you have vaginal bleeding of unknown cause;
 - if you have a vaginal infection with an accompanying discharge;
 - if you have, or previously had, blood clots (especially in the legs, the lungs or the heart);
 - if you have a known abnormality in blood coagulation;
 - if you recently had a heart attack;
 - if you recently experienced chest pains;
 - if you have a liver disease or a history of liver disease;
 - if you have porphyria;
 - if you are a girl who have not had your first menstrual cycle.

Warnings and precautions

Since a small amount of estriol can be absorbed through the vaginal mucosa into the blood, systemic effects of the hormone may appear.

Special care should be taken with GYNOFLOR:

- if you suffer from heart disease;
- if you suffer from liver disease;
- if you suffer from kidney disease;
- if you suffer from epilepsy;
- if you have increased cholesterol levels in your blood;
- if you suffer from high blood pressure;
- if you suffer from diabetes;
- if you suffer from migraines;
- if you suffer from asthma;
- if you suffer for porphyria;
- if you experience severe itching, skin blistering or hearing loss during pregnancy.

Children and adolescents

GYNOFLOR should not be given to girls who have not had their first menstrual cycle. **GYNOFLOR** should not be given to boys.

Other medicines and GYNOFLOR

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

Lactobacillus acidophilus is sensitive to various oral and locally applied antibiotic medicines. Simultaneous treatment may reduce the efficacy of **GYNOFLOR**.

Because of the very low estriol content in **GYNOFLOR** and the topical method of administration, interactions with other medicines are not expected.

No studies are available on possible interactions between **GYNOFLOR** and latex products (e.g. condoms, diaphragms, etc.). As a precaution, other methods of birth control should be used while using (and for the first few days after stopping) **GYNOFLOR**.

GYNOFLOR with food and drink

It is unlikely that food and beverages will make **GYNOFLOR** less effective if taken at the same time.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare professional for advice before using this medicine.

GYNOFLOR may be used during pregnancy and breastfeeding.

3. How to use GYNOFLOR

Do not share your medicines with any other person.

Always use **GYNOFLOR** exactly as described in this leaflet or as your doctor, pharmacist or other healthcare professional has told you. Check with your doctor, pharmacist or other healthcare professional if you are not sure.

Only for vaginal use.

One vaginal tablet daily for at least 12 days.

Subsequently a maintenance dose of 1 vaginal tablet at 2 to 3 days per week is recommended.

The vaginal tablets should be inserted deeply (about the depth of one finger) into the vagina in the evening before going to bed. The recommended position is to lie on the bed with your knees bent and tilted towards the chest.

If you use more GYNOFLOR than you should

No adverse effects are expected in the event of overdosage.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to use GYNOFLOR

If you miss a dose of **GYNOFLOR**, use it as soon as you remember.

However, if it is nearly time for the next dose, skip the missed dose.

Do not use a double dose to make up for forgotten individual doses.

4. Possible side effects

GYNOFLOR can have side effects.

Not all side effects reported for **GYNOFLOR** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using **GYNOFLOR**, please consult your healthcare professional for advice.

If any of the following happens, stop using GYNOFLOR and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to **GYNOFLOR**. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

- vaginal inflammation (redness, pain and swelling),
- vaginal burning and/or itching (especially at the start of treatment),

- vaginal discharge.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of **GYNOFLOR**.

5. How to store GYNOFLOR

- Store at 2 °C – 8 °C (in a refrigerator).
- Storage of **GYNOFLOR** at room temperature for 1 – 2 weeks does not affect its efficacy.
- Keep the blister strip in the outer carton until required for use.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use after the expiry date printed on the carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What GYNOFLOR contains

The active substances are *Lactobacillus acidophilus* and estriol.

Each **GYNOFLOR** vaginal tablet contains at least 1×10^8 cfu viable *Lactobacillus acidophilus* and 0,03 mg estriol.

The other ingredients are dibasic sodium phosphate (anhydrous), lactose monohydrate, magnesium stearate, microcrystalline cellulose (PH102) and sodium starch glycolate (Type A).

What GYNOFLOR looks like and contents of the pack

Vaginal tablets.

The vaginal tablets are white to beige, spotted, oval and biconvex.

PVC/PE/PVdC-aluminium foil blister strips.

Each blister strip contains 6 vaginal tablets.

Packs sizes: 6, 12, or 36.

Holder of Certificate of Registration

Adcock Ingram Limited

1 New Road,

Erand Gardens,

Midrand, 1685

South Africa

Customer Care: 0860 ADCOCK / 232625

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