SCHEDULING STATUS
S2

GYNOFLOR vaginal tablets
0,03 mg estriol / 1 x 10^8 cfu viable *Lactobacillus acidophilus*

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 health care 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 estrogen (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 estrogen in women, usually in post-menopausal women. Because of decreased estrogen, post-menopausal 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 estrogen-dependent cancer like breast cancer, ovarian cancer and endometrial (uterine) cancer which rely on estrogen 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 (effects of the medicine throughout the body) 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 health care provider 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 health care provider 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 health care provider has told you. Check with your doctor, pharmacist or other health care provider 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 health care provider 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 0,03 mg estriol and at least 1 x 10^8 cfu viable *Lactobacillus acidophilus*.

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.
Not all pack sizes may be marketed.

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