

Package Leaflet : Information for the User

Gynozol 200 mg Vaginal Soft Gelatin Capsules
Gynozol 400 mg Vaginal Soft Gelatin Capsules
Miconazole Nitrate

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, nurse or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

- 1-What Gynozol Vaginal Soft Gelatin Capsules Vaginal Soft Gelatin Capsules is and what it is used for.
- 2-What you need to know before you take Gynozol Vaginal Soft Gelatin Capsules.
- 3- How to take Gynozol Vaginal Soft Gelatin Capsules.
- 4- Possible side effects
- 5- How to store Gynozol Vaginal Soft Gelatin Capsules.
- 6- Content of the pack and other information.

1. What Gynozol Vaginal Soft Gelatin Capsules is and what it is used for

Gynozol Vaginal Soft Gelatin Capsules contains the active substance miconazole nitrate. It is an imidazole derivative with antifungal and anti - bacterial activity. The antifungal activity has been demonstrated in vitro, miconazole acts on mucocutaneous fungal infections:
- Dermatophytes (trichophyton, epidermophyton, microsporum)
- Candida and other yeasts.
- Malassezia furfur (agent of tinea capitis and tinea versicolor)
- Molds and other fungi.
The antibacterial activity has been demonstrated in vitro against gram positive bacteria.

Gynozol Vaginal Soft Gelatin Capsules is used for local treatment of vulvovaginal mycosis superinfected or not by gram - positive bacteria.

2. What you need to know before you take Gynozol Vaginal Soft Gelatin Capsules

- Do not take Gynozol Vaginal Soft Gelatin Capsules in case of:**
- Hypersensitivity to the active substance or any of the excipients (or cross sensitivity with other members of the imidazole group).
 - Using latex diaphragms or latex condoms.

Warnings and precautions

Warnings

- Gynozol Vaginal Soft Gelatin Capsules is not recommended:
- During lactation.
 - With spermicides (see interactions).
 - In absence of diagnosis of symptoms, the finding of candida on the skin or

mucous membranes cannot constitute in itself an indication.

- To confirm candidiasis, the ecological factors should be carefully observed for the development of the fungus. This is indispensable to avoid elapse, and for eradication or compensation of predisposing factors.
- It is advisable to treat simultaneously any recognized pathogenic candidate.

Precautions

- In case of local intolerance or allergic reaction, treatment with Gynozol Vaginal Soft Gelatin Capsules should be discontinued.
- It is not advisable to use a soap with acidic pH (pH favouring the multiplication of the candida).

Other medicines and Gynozol Vaginal Soft Gelatin Capsules

Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines, including medicines obtained without prescription and herbal medicines.

This is because Gynozol Vaginal Soft Gelatin Capsules can affect the way some medicines work and some medicines can have an effect on Gynozol Vaginal Soft Gelatin Capsules.

In particular, tell your doctor, pharmacist or nurse if you are taking any of the following medicines:

- Male condoms latex / latex diaphragm: risk of rupture of diaphragm or of the latex condom when used with vaginal capsules or lubricants containing mineral oils (Paraffin, Silicone,)
- Spermicides: All local vaginal treatment may inactivate local spermicidal contraception.

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. Studies on animals have shown no evidence of teratogenicity. In the absence of teratogenic effect in animals, teratogenicity in human is not expected. In fact, now substances responsible for the malformations in humans have proved to be teratogenic in the animals during well -conducted studies in two species. Clinical studies on pregnant women have showed no malformative or foetotoxic action of this medicine.
Your doctor will decide whether you should use Gynozol Vaginal Soft Gelatin Capsules.

As a precaution, this medication is not recommended during lactation, due to the absence of sufficient data on the secretion of miconazole nitrate in the milk. Therefore, your doctor will decide whether you should use Gynozol Vaginal Soft Gelatin Capsules while breast-feeding.

Driving and using machines

This medicine is not likely to affect you being able to drive or use machines have been performed.

3. How to use Gynozol Vaginal Soft Gelatin Capsules

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

In most cases, the duration of treatment is 3 days: insert deeply into the vagina



1 capsule at bedtime, preferable in reclining position. Complete the entire treatment, even if symptoms (for example: itching and vaginal discharge) have disappeared or if menstruation begins. In case of recurrent or severe mycosis, it may be advisable to prescribe a 6 day treatment.

Recommendations for use

- Wash hands thoroughly before and after administration of the product.
- Wash with soap of neutral or alkaline pH.
- The treatment will be accompanied by hygienic measures (wearing cotton underwear, avoid use of vaginal douching, ...) and to the possible extent, the elimination of predisposing factors.
- For treating the extension of vulvar or perianal fungus, it is recommended to combine Gynozol Vaginal Soft Gelatin Capsules vaginal soft gelatin capsules with antifungal cream applied locally.
- Do not interrupt the treatment during the menstruation.

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

4. Possible side effects

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

The following table presents the undesirable effects reported with the use of miconazole nitrate vaginally and classified by system and frequency using the following convention:

Very common (≥ 1/10), common (≥ 1/100 to < 1/10), uncommon (≥ 1/1000 to < 1/100), rare (≥ 1/10000 to < 1/1000), very rare (< 1/10000) and frequency not known (cannot be estimated from the available data).

Immune System disorders	
Frequency not known	Hypersensitivity including anaphylactic and anaphylactoid reactions, angioedema
Nervous system disorders	
Common	Headache
Gastrointestinal disorders	
Common	Abdominal pain, nausea.
Skin and subcutaneous tissue disorders	
Common	Rash
Uncommon	Face edema, urticaria
Not known	Itching
Reproductive system and breast disorders	
Very common	Female genital pruritus,
Common	Dysmenorrhoea, vaginal discharge, vaginal bleeding
Not known	Vaginal irritation.
General disorders and administration site	
Not known	Administration site reaction

5. How to store Gynozol Vaginal Soft Gelatin Capsules

Store at temperature not exceeding 30° C, in a dry place. Keep this medicine out of the sight and reach of children. Do not use this medicine after the expiry date which is stated on the blister or carton after {EXP}. 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 Gynozol Vaginal Soft Gelatin Capsules contains

The active substance is Miconazole nitrate. Each Gynozol 200 mg Vaginal Soft Gelatin Capsule contains Miconazole nitrate 200 mg. Each Gynozol 400 mg Vaginal Soft Gelatin Capsule contains Miconazole nitrate 400 mg.

The other ingredients are Liquid paraffin, Vaseline, Gelatin, Sorbitol, Glycerol, Sodium ethyl hydroxybenzoate, Sodium propyl hydroxybenzoate, Titanium dioxide powder, FD & C Yellow (**for Gynozol 200**), Cochineal red (**for Gynozol 400**).

What Gynozol Vaginal Soft Gelatin Capsules looks like and contents of the pack

Gynozol 200 mg Vaginal Soft Gelatin Capsules are light buff oval soft gelatin capsules containing white to off white content.

Gynozol 400 mg Vaginal Soft Gelatin Capsules are faint pink oval soft gelatin capsules containing white homogenous content.

The pack of Gynozol 200 mg Vaginal Soft Gelatin Capsules consists of a carton box containing 2 (Al/transparent PVC) blisters, each of 3 vaginal Soft Gelatin Capsules and insert leaflet.

The pack of Gynozol 400 mg Vaginal Soft Gelatin Capsules consists of a carton box containing one (Al/transparent PVC) blister of 3 vaginal Soft Gelatin Capsules and insert leaflet.

Marketing Authorization Holder and Manufacturer

Marketing Authorization Holder :

Pharco Pharmaceuticals
Km 31, Alexandria – Cairo desert road, Amriya, Alexandria, Egypt.

Manufacturer :

Safe for Pharmaceuticals (Safe Pharma)
New Borg El Arab city, 2nd Industrial Zone, Section No.3, Block 31, Alexandria, Egypt.

This leaflet was last revised in December 2024

