

Gynazole-1 Vaginal Cream

contains the active ingredient butoconazole nitrate



CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about GYNAZOLE-1.

It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you using GYNAZOLE-1 against the benefits they expect it will have for you.

If you have any concerns about using this medicine, talk to your doctor or pharmacist.

Keep this leaflet with your medicine. You may need to read it again.

What GYNAZOLE-1 is used for

GYNAZOLE-1 is used to treat candida infections of the vagina (thrush). This is a fungal infection, caused by overgrowth of yeast resulting in an imbalance of the natural micro-organisms present in the vagina. There are many reasons why this condition occurs. Examples include hormonal fluctuations (during certain times of the menstrual cycle or due to the use of the oral contraceptive pill), use of medications such as antibiotics and steroids, pregnancy, fatigue, stress and medical conditions such as diabetes.

Symptoms of thrush are discomfort, itchiness and discharge.

GYNAZOLE-1 belongs to a group of medicines called antifungals. It works by killing the yeast that causes the infection.

GYNAZOLE-1 is available only with a doctor's prescription.

Before you use GYNAZOLE-1

When you must not use it

Do not use GYNAZOLE-1 if you are allergic to medicines containing butoconazole nitrate or any of the ingredients listed at the end of this leaflet.

Do not use GYNAZOLE-1 if the expiry date (Exp.) printed on the pack has passed.

Do not use GYNAZOLE-1 if the packaging shows signs of tampering

Before you use it

Tell your doctor if you are pregnant.

GYNAZOLE-1 should only be used if your doctor considers it essential for your wellbeing, especially in the first three months of pregnancy.

Tell your doctor if you are breastfeeding.

It is not known whether GYNAZOLE-1 is excreted in breast milk.

Taking other medicines

No interactions with GYNAZOLE-1 have been reported.

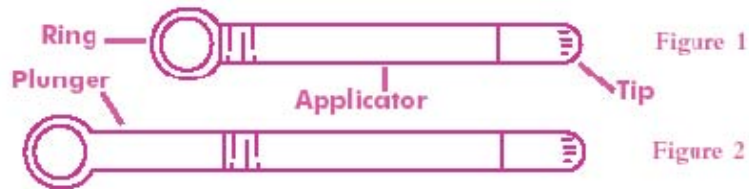
Some medications can cause vaginal thrush. Check with your doctor or pharmacist if you are on other medications.

How to use GYNAZOLE-1

3 Steps to Using the GYNAZOLE-1 Vaginal Cream, 2.0% Prefilled Disposable Applicator

Step 1: Preparing the Applicator

Peel back the protective foil and remove the prefilled applicator. Applicator is designed to be used with tip in place. Do *not* remove tip; do *not* use applicator if tip has been removed.

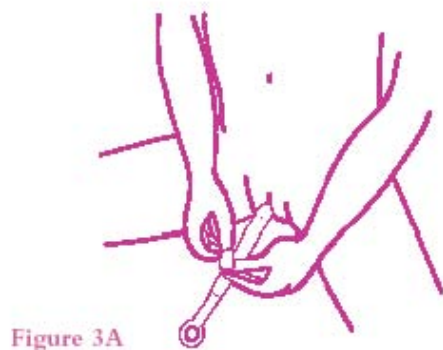


Do not warm applicator before using. While holding the applicator firmly, pull the ring back to *fully* extend the plunger (See Figure 2).

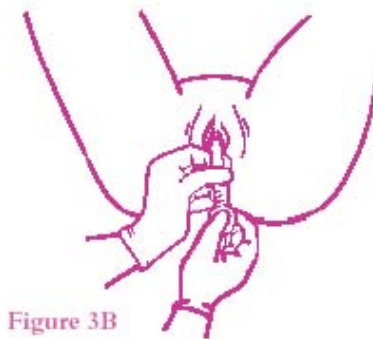
Step 2: Inserting the Applicator

Gently insert the applicator into the vagina as far as it will comfortably go (See Figure 3).

Patient Administered



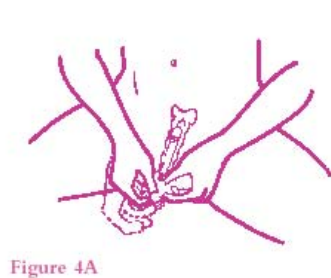
Professionally Administered



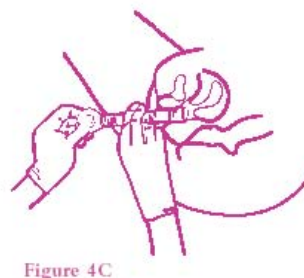
Step 3: Applying the Cream

Push the plunger to release the cream (See Figure 4). Remove the empty applicator from the vagina and throw it away.

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Important Instructions:

- One prefilled applicator of Butoconazole Nitrate Vaginal Cream, 2.0% should be administered.

Hygienic precautions

In order to avoid the possibility of reinfection, strict personal hygiene must be observed. Wash your hands thoroughly before inserting the applicator into the vagina.

The following measures, as well as your usual hygiene routine, may help considerably in preventing reinfection.

- After urinating, the toilet tissue should be used as a blotter, rather than used with a forward or backward motion. Similarly, to avoid the possibility of spreading organisms from the rectum to the vaginal tract after a bowel movement, a wiping motion away from the vagina should be used when applying toilet tissue.
- Underwear, night attire, towels and linen should be changed daily.

While you are using GYNAZOLE-1

Things you must do

It is important to note the following points while you are being treated with GYNAZOLE-1.

- Wash hands thoroughly before applying the cream.
- To prevent reinfection, strict personal hygiene must be observed.
- Inform your physician if the area of application shows signs of increased irritation (redness, itching, burning).
- Treatment should be timed so as to avoid the menstrual period and to be finished before the onset of menstruation.
- During pregnancy, the applicator should only be used on the advice of your doctor. If you are pregnant, strictly follow the instructions of your doctor.
- Avoid sources of infection or reinfection.
- The cream should be applied after your bath or shower, preferably in the evening.
- Avoid wearing tight, restrictive clothing.
- If you are sexually active, ask your doctor or pharmacist if it is necessary to treat your partner as well.
- Do not douche or use tampons during the course of your treatment.

See your doctor or pharmacist if you are not better after the recommended treatment.

One dose of Gynazole-1 should clear up your symptoms. It is recommended that you consult your doctor or pharmacist should symptoms persist after treatment.

Gynazole-1 is inserted directly into the vagina using the applicator. Another topical antifungal cream may also be required to treat the external vulval area.

Things to be careful of

Do not use latex or rubber products such as condoms or diaphragms within 72 hours of using GYNAZOLE-1. GYNAZOLE-1 contains mineral oil which may weaken latex or rubber products.

Increased discharge or leakage of the cream from the vagina may occur onto underwear and clothing. Patients may wish to use a sanitary napkin to stop the cream contacting clothing. A tampon should not be used for this purpose.

Side effects

GYNAZOLE-1 is generally well tolerated. However, you may experience some of the following:

- Local irritation including burning or stinging, itching, redness or swelling.
- Discharge or leakage of the cream from the vagina.

If you are concerned by any of these reactions, consult your doctor.

After using GYNAZOLE-1

Storage

Keep GYNAZOLE-1 in the original packaging until you need to use it.

Store below 25°C in a dry place, out of the reach of children.

Product description

What it looks like

GYNAZOLE-1 is a prefilled applicator ready for use. It applies approximately 5 g of cream into the vagina.

Ingredients

The active ingredient in GYNAZOLE-1 is butoconazole nitrate. Each application of GYNAZOLE-1 contains approximately 100 mg of butoconazole nitrate.

The cream also contains:

- sorbitol solution
- propylene glycol
- disodium edetate
- mineral oil
- polyglyceryl-3 oleate
- glycerol isostearate
- microcrystalline wax
- silica dimethyl silylate
- methyl hydroxybenzoate
- propyl hydroxybenzoate.

Supplier

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Australian registration numbers:
AUST R 107327

Date of preparation:
April 2006

GYNAZOLE-1_042006-1