

PACKAGE LEAFLET: INFORMATION FOR THE USER

Canesten gyno 3, cream for vaginal use 20 mg/g
clotrimazole

Read the entire leaflet carefully before you start using this medicine because it contains important information for you.

Keep this leaflet. You may need to read it again.

Do you have any questions? Please contact your doctor or pharmacist.

Do not pass this medicine on to others, as it has been prescribed for you only. It may harm them, even if their symptoms are the same as yours.

Do you experience any side effects listed in section 4? Or do you experience a side effect not mentioned in this leaflet? Then contact your doctor or pharmacist.

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1. WHAT IS CANESTEN GYNO 3 AND WHAT IS THIS MEDICINE USED FOR?

Canesten gyno 3 contains the active ingredient clotrimazole. Clotrimazole is a substance that kills certain types of fungi or yeasts or inhibits their growth inhibits it.

Your doctor has diagnosed a fungal infection in the vagina. The most common cause is *Candida albicans*. This fungus is normally present on the skin and can cause complaints under certain conditions, such as the development of vaginal discharge, known as leucorrhea. Canesten gyno 3 is used for infections of the vagina caused by certain types of fungi or yeasts.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE THIS MEDICINE

When should you not use this medicine?

You are allergic to any of the ingredients in this medicine, such as cetylstearyl alcohol. You can find these substances in section 6. When should you be extra careful with this medicine?

Canesten gyno 3 vaginal cream should not be used during menstruation, as the effectiveness cannot be fully relied upon. Therefore, ensure that the treatment is completed before that time.

This medicine contains 2 grams of benzyl alcohol in every 100 grams of cream, equivalent to 20 mg/g cream. Benzyl alcohol can cause mild local irritation.

The vaginal cream should not be used in case of hypersensitivity to cetylstearyl alcohol, as this substance is used as an excipient in the cream (100 mg per gram). In that case, the (also

commercially available) vaginal tablet can be used. Cetylstearyl alcohol can cause local skin reactions (e.g., contact dermatitis).

Canesten gyno 3 cream can reduce the effectiveness and safety of rubber products such as condoms and diaphragms. The effect is temporary and only occurs during treatment.

Use of Canesten gyno 3 in combination with other medicines
No interactions of Canesten gyno 3 with other medicines are known.

Tell your doctor or pharmacist if you are using or have recently used other medicines. This also applies to medicines you can use without a prescription.

Pregnancy, breastfeeding, and fertility

Pregnancy

Canesten gyno 3 can, as far as is known, be used without danger to the fetus in the recommended dosage during pregnancy, if necessary. During pregnancy, the use of the applicator should be avoided and administration of the (also commercially available) vaginal tablets by hand is preferred. The vaginal tablet can be inserted by hand inserted.

Breastfeeding

Canesten gyno 3 can be used according to the prescription during breastfeeding.

Fertility

No studies have been conducted in humans on the effects of clotrimazole on fertility, but animal studies have shown no effect of the drug on fertility.

Are you pregnant, do you think you might be pregnant, do you want to become pregnant, or are you breastfeeding? Then contact your doctor or pharmacist before using this medicine.

Driving and using machines

It is not expected that this medicine will affect these functions.

3. HOW TO USE THIS MEDICINE?

Follow the advice of your doctor closely when using Canesten gyno 3. Consult your doctor or pharmacist if in doubt.

In general, your doctor's prescription will be: for three consecutive days, once a day - in the evening before going to bed - insert one applicator filling (approx. 5 grams) of vaginal cream as deeply as possible into the vagina. A new applicator should be used for each administration, which can then be discarded.

When the infection has also spread outside the vagina, around the labia, to prevent reinfection, a prescription from the doctor may also include clotrimazole cream for vaginal use 10 mg/g. Apply this cream thinly to the affected areas twice a day for about one week.

Instructions for use

The insertion of the vaginal cream is best done in a supine position, with slightly raised and spread legs.

Canesten gyno 3 vaginal cream is administered as follows:

1. Open the tube by pressing the cap of the tube inverted through the aluminum seal.
2. Pull the plunger of the applicator out to the stop.
3. Place the applicator on the tube, hold it firmly, and fill it completely by gently squeezing the tube.
4. Remove the applicator from the tube, insert it as deeply as possible into the vagina (best in a supine position), and empty it by pressing the plunger.
5. Remove and discard the applicator.

General

The partner should be treated with an antifungal cream if there is an infection of the penis to prevent mutual contamination.

In persistent infections, consider a possible infection via the rectum, which should then be treated.

If you notice that Canesten gyno 3 is too strong or too weak, consult your doctor or pharmacist.

Consult a doctor if the symptoms persist for more than 7 days.

Have you used too much of this medicine?

There are no known cases of overdose with the use of Canesten gyno 3 according to the instructions for use.

If in doubt, contact your doctor or pharmacist.

Have you forgotten to use this medicine?

In that case, you can apply the normal dosage at the next time. Do not use a double dose to make up for a forgotten dose in .

4. POSSIBLE SIDE EFFECTS

Like any medicine, this medicine can have side effects , although not everyone experiences them. The following side effects have been observed with unknown frequency during the use of clotrimazole.

Immune system disorders: hypersensitivity in severe cases leading to swelling of the lips, tongue, and throat or an anaphylactic reaction (may be accompanied by nausea, diarrhea, lowered blood pressure, difficulty breathing, unconsciousness).

Skin and subcutaneous tissue disorders: red skin, itchy rash, skin rash, tingling/burning sensation of the skin.

General disorders and administration site conditions: irritation or reaction at the administration site, fluid retention. When using the cream, irritation of the partner's penis may occur.

Reproductive system and breast disorders: vaginal bleeding.

Reporting side effects

If you experience side effects, contact your doctor or pharmacist. This also applies to possible side effects not listed in this leaflet. You can also report side effects directly via www.lareb.nl. By reporting side effects, you can help us obtain more information about the safety of this medicine.

5. HOW TO STORE THIS MEDICINE?

Keep out of the sight and reach of children.

For Canesten gyno 3 cream, there are no special storage conditions.

Do not use this medicine after the expiry date which is stated on the label on the packaging after "EXP:". The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or with household waste. Ask your pharmacist what to do with medicines you no longer need. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What substances are in this medicine?

Canesten gyno 3 is a cream for vaginal use. The active substance in this medicine is clotrimazole.

Other excipients in this medicine are: sorbitan stearate (E491), polysorbate 60

(E435), cetylstearyl alcohol, cetyl palmitate, 2-octyldodecanol, benzyl alcohol, purified water.

What does Canesten gyno 3 look like and how much is in a package?

Canesten gyno 3 vaginal cream is available in a package with a tube containing 20 grams of cream and 3 applicators.

Marketing authorization holder and manufacturer

Registration holder:

Euro Registratie Collectief b.v.

Kempkens 2200

5465 PR Veghel

Ompakker (see label on the outer packaging):

Brocef B.V., Maroastraat 43, 1060 LG Amsterdam

or

Stephar B.V., Kempkens 2200, 5465 PR Veghel

Manufacturer:
Kern Pharma S.A.
Terrassa
Spain

Bayer Healthcare AG
Leverkusen
Germany

Famar AB
Avlonas Attikis
Greece

GP Grenzach Produktions GmbH
Grenzach-Wyhlen
Germany

Registered under:
RVG 121639//08935 Canesten gyno 3, cream for vaginal use 20 mg/g (Greece)

This medicine is marketed in the country of origin under the name:
Greece: Canesten 2% κολπική κρέμα

This leaflet was last approved in March 2025 ((130225)).