

## LEAFLET: INFORMATION FOR THE USER

Canesten gyno 3, cream for vaginal use 20 mg/g  
Canesten gyno 3, tablet for vaginal use 200 mg  
Active substance: 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 further questions? Please ask your doctor or pharmacist.

Do not pass this medicine on to others, as it is prescribed only for you.

It may harm them, even if their symptoms are the same as yours.

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

### Contents of this leaflet

1. What is Canesten gyno 3 and what is this medicine used for
2. What you need to know before you use this medicine
3. How to use this medicine?
4. Possible side effects
5. How do you store this medicine?
6. Contents of the package and other information

## 1. WHAT IS Canesten gyno 3 AND WHAT IS THIS MEDICINE USED FOR

Canesten gyno 3 contains the active substance clotrimazole. Clotrimazole is a substance that certain fungi or yeast species kill or inhibit their growth.

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 present and can cause symptoms under certain conditions, such as the development of vaginal discharge, known as leucorrhoea. 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 and Canesten gyno 3 vaginal tablet should not be used during menstruation, as the effectiveness cannot be fully relied upon. Therefore, ensure that the course is completed before that time.

This product 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. In that case, the vaginal tablet can be used. Cetylstearyl alcohol can cause local skin reactions (e.g., contact dermatitis).

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

Use of Canesten gyno 3 in combination with other medications There are no interactions of Canesten gyno 3 with other known medicines.

Tell your doctor or pharmacist if you are using or recently have used. 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 risk to the fetus in the recommended dosage during pregnancy, if necessary. During pregnancy, the use of the applicator should be avoided, and administering the vaginal tablets by hand is preferred. The vaginal tablet can be inserted by hand. 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 vaginal tablets by hand is preferred. The vaginal tablet can be inserted by hand.

##### Canesten

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

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 abilities.

### 3. HOW TO USE THIS MEDICINE?

When using Canesten Gyno 3, follow your doctor's advice closely. Consult your doctor or pharmacist if in doubt.

#### Canesten gyno 3 vaginal cream

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 full (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.

#### Canesten gyno 3 vaginal tablet

In general, your doctor's prescription will be: for three consecutive days, once a day - in the evening before going to bed - insert one Canesten gyno 3 vaginal tablet as deeply as possible into the vagina.

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

#### Instructions for use

The insertion of the vaginal cream and vaginal tablet 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 rod of the applicator out to the stop.
3. Place the applicator on the tube, hold it firmly pressed, and fill completely by gently squeezing the tube.
4. Remove the applicator from the tube, insert as deeply as possible into the vagina (preferably in a supine position) and empty by pressing the rod.
5. Remove and discard the applicator.

Canesten gyno 3 vaginal tablet is administered as follows:

#### Administration using the supplied applicator

The applicator is used to insert the tablet as deeply as possible into the vagina, preferably before going to bed.

Wash your hands before removing the vaginal tablet and the applicator from the packaging and after using the applicator.

1. Remove the applicator from the packaging and pull the rod to the red lock out.
2. Place the vaginal tablet in the open end of the applicator with the rounded side of the vaginal tablet facing down. Push the rod and lock the applicator until it clicks.
3. Then remove the lock from the rod and carefully insert the applicator into the vagina up to the notch.
4. Hold the applicator at the notch and gently push the rod all the way in to insert the vaginal tablet until it can go no further.
5. After use, disassemble the parts and wash them thoroughly in warm (not boiling) soapy water. Rinse them for 30 seconds with clean water and wipe the parts carefully. Store it in a clean and safe place. For reuse, ensure the red lock is replaced on the rod and repeat the

process from step 2. Dispose of the applicator safely after the last use, out of reach of children. The applicator should not be flushed down the toilet.

#### Administration without applicator

Hold the labia apart with the free hand and gently press the tablet with the rounded side up and the finger against the flat side of the tablet as deeply as possible into the vagina.

#### General

The partner should be treated with an antifungal cream in case of penile infection to prevent mutual contamination.

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

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The tablets need moisture in the vagina to dissolve completely.

Undissolved particles of the tablet may be expelled from the vagina. To prevent this, it is important to insert the tablet as deeply as possible into the vagina before going to sleep. If the tablet does not dissolve in one night, consider using a using clotrimazole containing cream. If you notice that

Canesten gyno 3 is too strong or not effective enough, consult your doctor or pharmacist. 3 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. Consult your doctor if the tablet is accidentally taken orally, ingested.

If in doubt, contact your doctor or pharmacist.

Have you forgotten to use this medicine use? In that case, you can apply the normal dosage at the

next scheduled time. Do not use a double dose to make up for a forgotten dose.

#### 4. POSSIBLE SIDE EFFECTS

Like any medicine, this medicine can have side effects, although not everyone gets them. The following side effects have been identified 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. Use of the cream and tablet may cause irritation of the partner's penis.

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](http://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. Store Canesten gyno 3 tablet below 25°C. After opening the tube, Canesten gyno 3 cream is usable for 3 months.

Do not use this medicine after the expiry date which is stated on the box, the tube, or on the blister strip 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 medicine available in two forms, a vaginal cream and a vaginal tablet. The active substance in this medicine is clotrimazole.

Other excipients in this medicine are:

Canesten gyno 3 cream: sorbitan stearate (E 491), polysorbate 60 (E 435), cetylstearyl alcohol, cetyl palmitate, 2-octyldodecanol, benzyl alcohol, water.

Canesten gyno 3 tablet: calcium lactate (E327), colloidal silicon dioxide (E551), crospovidone (E1202), lactose, magnesium stearate (E470B), corn starch, lactic acid (E270), microcrystalline cellulose (E460 (i)), hypromellose (E464).

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.

Canesten gyno 3 vaginal tablet is available in a package with 3 tablets and an applicator.

Marketing authorization holder and manufacturer

Registration holder: Bayer B.V., Siriusdreef 36, 2132 WT Hoofddorp

For information: Consumer Health Division, P.O. Box 88, 2130 AB Hoofddorp.

Manufacturer

Canesten gyno 3 cream: Kern Pharma, s.l, Terrassa, Spain.

GP Grenzach Produktions GmbH, Grenzach-Wyhlen, Germany.

Canesten gyno 3 tablet: GP Grenzach Produktions GmbH, Grenzach-Wyhlen, Germany.

Canesten gyno 3 vaginal cream is registered under RVG 08935.

Canesten gyno 3 vaginal tablet is registered under RVG 08934.

This leaflet was last approved in August 2022.