

APPROVED  
By rajeevkumarj at

MOCK-UP

Package Leaflet: Information for the User

**Canesten® 2% Thrush Cream**  
(clotrimazole)**Read all of this leaflet carefully because it contains important information for you.**

This medicine is available without prescription. However, you still need to use Canesten Thrush Cream carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve in 7 days.
- If you have any unusual effects after using this product, tell your doctor or pharmacist.
- The name of your medicine is Canesten 2% Thrush Cream but will be referred to as Canesten Thrush Cream throughout the remainder of this leaflet.

**In this leaflet**

1. What is Canesten Thrush Cream and what is it used for?
2. Before you use Canesten Thrush Cream
3. How to use Canesten Thrush Cream
4. Possible side effects
5. How to store Canesten Thrush Cream
6. Further information

**1. What is Canesten Thrush Cream and what is it used for?**

Canesten Thrush Cream relieves irritation of the vulva (vulvitis) which is caused by vaginal thrush (candidiasis).

Although this cream provides relief from the external irritation caused by vaginal thrush, it cannot treat any internal (vaginal) cause of the infection. Ask your doctor or pharmacist to recommend a treatment for this.

**Only use this product if you have been previously diagnosed by your doctor as having vaginal thrush.**

Some women suffer from recurrent attacks of thrush. To reduce the frequency of these attacks, the sexual partner's penis can be treated with this cream to prevent re-infection, even if they have no symptoms of thrush.

The active substance in Canesten Thrush Cream is clotrimazole. Clotrimazole belongs to a group of medicines called azoles and is an antifungal agent which fights the cause of infections such as vaginal thrush.

**2. Before you use Canesten Thrush Cream****Do not use Canesten Thrush Cream:**

- If you are allergic (hypersensitive) to clotrimazole or any of the other ingredients, including cetostearyl alcohol or benzyl alcohol, of Canesten Thrush Cream (see Section 6. Further Information).

**Before using Canesten Thrush Cream, you should see your doctor if:**

- You are unsure whether you have thrush or this is the first time you have had these symptoms.
- You have had more than two infections of thrush in the last six months.
- You or your partner have ever had a sexually transmitted disease.
- You are aged under 16 or over 60.
- You have ever had an allergic reaction to Canesten or any other vaginal antifungal products.
- You have any of the following symptoms:
  - Irregular vaginal bleeding.
  - Abnormal vaginal bleeding or a blood stained discharge.
  - Ulcers, blisters or sores of the vagina or vulva.
  - Lower abdominal pain.
  - Pain or difficulty in passing urine.
  - Fever or chills.
  - Feeling sick or vomiting.
  - Diarrhoea.
  - A foul smelling discharge from the vagina.

This is because Canesten Thrush Cream may not be the right treatment for you.

**Important information about some of the ingredients:**

This product contains cetostearyl alcohol which may cause local skin reactions (e.g. contact dermatitis). The medicine also contains 20mg benzyl alcohol in each gram of cream. Benzyl alcohol may cause allergic reactions and mild local irritation.

**Special precautions:**

As with other creams, this product may reduce the effectiveness of rubber contraceptives, such as condoms or diaphragms. Consequently, you should use alternative precautions for at least five days after using this product.

**Pregnancy and breast-feeding:**

If you are pregnant, breast-feeding or trying for a baby, tell your doctor or midwife before using Canesten Thrush Cream. If you have informed your doctor or midwife already, follow his/her instructions carefully.

**3. How to use Canesten Thrush Cream****Women:**

If Canesten Thrush Cream has been prescribed for you by your doctor, follow any instructions he/she may have given you. If you purchased this product without a prescription, follow these directions closely:

- Before use, pierce the tube seal by inverting the cap over the end of the tube and press.
- To treat the itching and soreness of the vulva (vulvitis), the cream should be thinly and evenly applied to the area around the entrance of the vagina, 2 or 3 times a day and smoothed in gently. A product to treat the internal (vaginal) infection should be used at the same time.

Treatment should be continued until symptoms of the infections disappear. Consult your doctor if the symptoms of your infection do not improve within seven days of finishing treatment for the internal infection.

**Treating your sexual partner:**

If your sexual partner is treated with this cream, the cream should be applied to the end of the penis 2 or 3 times a day for up to two weeks.

**Canesten Thrush Cream is for external use only:****Do not put the cream in your mouth or swallow it.**

If the cream is swallowed accidentally, tell your doctor straight away or contact the Accident and Emergency Department of your nearest hospital.

**4. Possible side effects**

Like all medicines, Canesten Thrush Cream can cause side effects, although not everybody gets them.

As with all medicines, some people may be allergic to the cream. If you are allergic, a reaction will occur soon after you have used the medicine. If you experience an allergic reaction or the redness, burning, pain, itching or swelling get worse, stop using this product and tell your doctor straight away or contact the Accident and Emergency Department of your nearest hospital. Signs of an allergic reaction may include:

- Rash.
- Swallowing or breathing problems.
- Swelling of your lips, face, throat or tongue.
- Weakness, feeling dizzy or faint.
- Nausea.

After you apply the cream you might experience:

- Itching, rash, blisters, burning, discomfort, swelling, redness, irritation or peeling of skin.

If you experience any of the above effects, tell your doctor or pharmacist immediately.

### Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at:

[www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**.

By reporting side effects you can help provide more information on the safety of this medicine.

### 5. How to store Canesten Thrush Cream

- Keep out of the sight and reach of children.
- This medicinal product does not require any special storage conditions.
- Store in the original packaging.
- Do not use your cream after the expiry date which is stated on the carton/label and tube. The expiry date refers to the last day of the month.
- If your medicine becomes discoloured or shows any sign of deterioration return it to your pharmacist.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

### 6. Further information

#### What Canesten Thrush Cream contains:

One 20g tube of Canesten Thrush Cream contains clotrimazole 400mg (2% w/w).

The other ingredients are sorbitan stearate, polysorbate 60, cetyl palmitate, cetostearyl alcohol, octyldodecanol, benzyl alcohol and purified water.

See Section 2 'Do not use' and 'Important information about some of the ingredients' for cetostearyl alcohol advice.

#### What Canesten Thrush Cream looks like and contents of the pack

Canesten Thrush Cream is a white cream available in 20g tubes.

Manufactured by

KERN PHARMA, S.L., Poligono Ind. Colon II. C/ Venus, 72, 08228 Terrassa (Barcelona), Spain.

GP Grenzach Produktions GmbH, Emil-Barell-Strasse 7, 79639 Grenzach-Wyhlen, Germany.

Procured from within the EU by Product Licence holder:

MPT Pharma Ltd., Westgate Business Park, Unit 5-7 Tintagel Way, Aldridge, Walsall WS9 8ER, UK.

Repackaged by MPT Pharma Ltd.

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Canesten® is a registered trademark of Bayer Intellectual Property GmbH.

**To request a copy of this leaflet in Braille, large print or audio please call 01922 745645 and ask for the Regulatory Department.**

**Remember: If you have any doubts about using Canesten Thrush Cream correctly, seek the advice of your doctor or pharmacist.**

#### Further information about vaginal thrush:

Vaginal thrush (candidiasis) is a common infection that most women suffer from at some time in their lives and is not caused by lack of personal hygiene.

Thrush is caused by a yeast (fungus) called Candida which lives harmlessly in the vagina and other parts of the body, without you even noticing it. However, the natural balance that keeps Candida under control can be upset by many factors such as hormonal changes (menstruation, contraceptive pill, pregnancy, menopause), poor health, antibiotics, perfumed soaps, bath additives and tight clothing.

If the natural pH balance is altered, the level of yeast increases and can develop into a thrush infection causing any of the following symptoms: persistent burning and/or itching around the vagina and vulva, redness, swelling and soreness of the tissues of the vagina and vulva and a whitish, odourless discharge from the vagina. Not everybody who has thrush has all these symptoms; you may have only one of them.

#### How to avoid future recurrences:

- ✓ Wear cotton knickers and loose clothing.
- ✓ Wash daily.
- ✓ After going to the toilet, wipe yourself from the front to back as a thrush infection may be transferred from the bowel.
- ✓ Change your sanitary protection regularly.
- ✗ Try to avoid wearing tights, nylon knickers and close fitting jeans.
- ✗ Try to avoid washing with perfumed soaps or using vaginal deodorants.
- ✗ Do not wash or rub yourself hard with sponges or flannels and avoid hot baths with strong perfumed oils.

If you are still worried or have any questions about the symptoms or the treatment of thrush, do not hesitate to ask your doctor or pharmacist for advice.

## Package Leaflet: Information for the User

# Clotrimazole 2% w/w cream

### Read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription. However, you still need to use Clotrimazole cream carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve in 7 days.
- If you have any unusual effects after using this product, tell your doctor or pharmacist.
- The name of your medicine is Clotrimazole 2% w/w cream but will be referred to as Clotrimazole cream throughout the remainder of this leaflet.

### In this leaflet

1. What is Clotrimazole cream and what is it used for?
2. Before you use Clotrimazole cream
3. How to use Clotrimazole cream
4. Possible side effects
5. How to store Clotrimazole cream
6. Further information

### 1. What is Clotrimazole cream and what is it used for?

Clotrimazole cream relieves irritation of the vulva (vulvitis) which is caused by vaginal thrush (candidiasis).

Although this cream provides relief from the external irritation caused by vaginal thrush, it cannot treat any internal (vaginal) cause of the infection. Ask your doctor or pharmacist to recommend a treatment for this.

### Only use this product if you have been previously diagnosed by your doctor as having vaginal thrush.

Some women suffer from recurrent attacks of thrush. To reduce the frequency of these attacks, the sexual partner's penis can be treated with this cream to prevent re-infection, even if they have no symptoms of thrush.

The active substance in Clotrimazole cream is clotrimazole. Clotrimazole belongs to a group of medicines called azoles and is an antifungal agent which fights the cause of infections such as vaginal thrush.

### 2. Before you use Clotrimazole cream

#### Do not use Clotrimazole cream:

- If you are allergic (hypersensitive) to clotrimazole or any of the other ingredients, including cetostearyl alcohol or benzyl alcohol, of Clotrimazole cream (see Section 6. Further Information).

#### Before using Clotrimazole cream, you should see your doctor if:

- You are unsure whether you have thrush or this is the first time you have had these symptoms.
- You have had more than two infections of thrush in the last six months.
- You or your partner have ever had a sexually transmitted disease.
- You are aged under 16 or over 60.
- You have ever had an allergic reaction to Clotrimazole or any other vaginal antifungal products.
- You have any of the following symptoms:
  - Irregular vaginal bleeding.
  - Abnormal vaginal bleeding or a blood stained discharge.
  - Ulcers, blisters or sores of the vagina or vulva.
  - Lower abdominal pain.
  - Pain or difficulty in passing urine.
  - Fever or chills.
  - Feeling sick or vomiting.
  - Diarrhoea.
  - A foul smelling discharge from the vagina.

This is because Clotrimazole cream may not be the right treatment for you.

### Important information about some of the ingredients:

This product contains cetostearyl alcohol which may cause local skin reactions (e.g. contact dermatitis). The medicine also contains 20mg benzyl alcohol in each gram of cream. Benzyl alcohol may cause allergic reactions and mild local irritation.

### Special precautions:

As with other creams, this product may reduce the effectiveness of rubber contraceptives, such as condoms or diaphragms. Consequently, you should use alternative precautions for at least five days after using this product.

### Pregnancy and breast-feeding:

If you are pregnant, breast-feeding or trying for a baby, tell your doctor or midwife before using Clotrimazole cream. If you have informed your doctor or midwife already, follow his/her instructions carefully.

### 3. How to use Clotrimazole cream

#### Women:

If Clotrimazole cream has been prescribed for you by your doctor, follow any instructions he/she may have given you. If you purchased this product without a prescription, follow these directions closely:

- Before use, pierce the tube seal by inverting the cap over the end of the tube and press.
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Treatment should be continued until symptoms of the infections disappear. Consult your doctor if the symptoms of your infection do not improve within seven days of finishing treatment for the internal infection.

#### Treating your sexual partner:

If your sexual partner is treated with this cream, the cream should be applied to the end of the penis 2 or 3 times a day for up to two weeks.

#### Clotrimazole cream is for external use only:

#### Do not put the cream in your mouth or swallow it.

If the cream is swallowed accidentally, tell your doctor straight away or contact the Accident and Emergency Department of your nearest hospital.

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Like all medicines, Clotrimazole cream can cause side effects, although not everybody gets them.

As with all medicines, some people may be allergic to the cream. If you are allergic, a reaction will occur soon after you have used the medicine. If you experience an allergic reaction or the redness, burning, pain, itching or swelling get worse, stop using this product and tell your doctor straight away or contact the Accident and Emergency Department of your nearest hospital. Signs of an allergic reaction may include:

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