**PACKAGE LEAFLET:**
**INFORMATION FOR THE PATIENT**

# Clotrimazole 500 mg

Vaginal Tablet

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- You must contact a doctor if your symptoms worsen or do not improve in 7 days.
- If you get any side effects after using this product, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet:**


1. What Clotrimazole is and what it is used for
2. What you need to know before you use Clotrimazole
3. How to use Clotrimazole
4. Possible side effects
5. How to store Clotrimazole
6. Contents of the pack and other information


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

This medicinal product contains Clotrimazole which belongs to a group of medicines called azoles and is an anti-fungal agent which fights the cause of infections such as vaginal thrush.

Clotrimazole 500mg **vaginal** tablet is a single application for the treatment of **vaginal** thrush (candidal vaginitis). It is inserted into the **vagina** for treatment at the site of infection (see section 3, "How to use Clotrimazole").

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

## 2. What you need to know before you use Clotrimazole

**Do not use Clotrimazole:**

- If you are allergic to Clotrimazole, azoles or any of the other ingredients of this medicinal product (listed in section 6)
- During your period as it may be less effective

**Warnings and precautions**

**Talk to your doctor before using Clotrimazole:**

- If you are unsure whether you have thrush or this is the first time you have had these symptoms
- If you have had more than 2 infections of thrush in the last 6 months
- If you or your partner have ever had a sexually transmitted disease
- If you are aged under 16 or over 60 years of age
- If you have ever had an allergic reaction to Clotrimazole or any other vaginal antifungal products
- You have any of the following symptoms:
  - o Irregular vaginal bleeding
  - o Abnormal vaginal bleeding or a blood-stained discharge
  - o Ulcers, blisters or sores of the vagina or vulva
  - o Lower abdominal pain
  - o Pain or difficulty passing urine
  - o Fever or chills
  - o Feeling sick (nausea) or being sick (vomiting)
  - o Diarrhoea
  - o A foul-smelling vaginal discharge

This is because Clotrimazole 500mg vaginal tablet may not be the right treatment for you.

**Special precautions:**

This product may reduce the effectiveness of rubber contraceptives, such as condoms or diaphragms. Consequently, you should use alternative precautions for at least 5 days after using this product.

Do not use tampons, intravaginal douches (vaginal washes/cleansers), spermicides or other vaginal products while using this product.

Avoid vaginal intercourse while you have thrush and during use of this product because your partner could become infected.

**Other medicines and Clotrimazole**

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

Inform your doctor if you are taking tacrolimus or sirolimus (used to reduce the immune response to prevent rejection after an organ transplant).

**Pregnancy and Breast-feeding**

Clotrimazole vaginal tablet can be used in pregnancy and breastfeeding.

If you are pregnant or think you may be pregnant, ask your doctor or midwife for advice before using this medicinal product.

If you have informed your doctor or midwife, follow their instructions carefully.

To treat internal thrush, your doctor may recommend that you insert the vaginal tablet without the help of the applicator.

## 3. How to use Clotrimazole

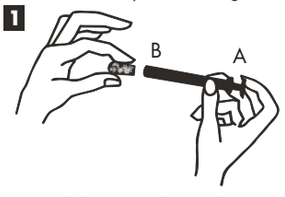
**If this medicinal product has been prescribed for you by your doctor, follow any instructions they may have given to you. If you purchased this product without a prescription, follow these directions closely. Check with your doctor or pharmacist if you are not sure.**

- Treatment consists of one vaginal tablet, which should be inserted into the vagina at night.

**Instructions how to insert Clotrimazole Vaginal Tablet**

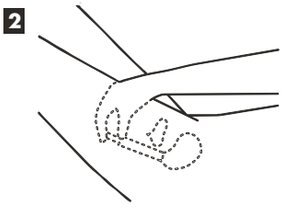
- Wash your hands before and after inserting the **vaginal** tablet
- Remove the applicator from the packaging
- Remove the tablet from the aluminium package and place it firmly into the open end of the disposable applicator "B" (Diagram 1)
- To fit the tablet into the applicator, squeeze the applicator lightly on both sides, whilst pushing the tablet far enough into the holder (about 1cm) to be held in place during insertion

1




- Carefully insert the applicator into the vagina as deeply as is comfortable. This is easiest when lying on your back with your legs slightly bent (Diagram 2)

2



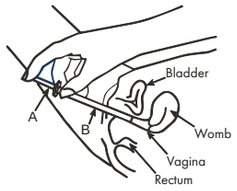

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|---|---|---|---|---|---|
| **Product Name** | Clotrimazole 500 mg VT | **Sap code :** | 1503304-4 | **Reference Artwork** | 1503304-3 |
| **Packaging Material** | Package leaflet | **Reason of change :** | TW140325 (.com) | Proof 1 | 08/08/2024 |
| **Size :** Foil Width | | **Country :** | UK | | |
| **Size :** Foil Repeat Length | | **Pack Size :** | All | | |
| **Size :** Strip Size | | **Barcode No. :** | [NA] | | |
| **Size :** PI - Open Size | 150 mm (w) x 300 mm (L) | **Pharmacode :** | 590 | | |
| **Size :** Carton/Label | | **No. of colours :** | 1 | | |
| **PM Style/Type :** | | **Min. Font Size :** | 9 points (Reg text) | | |
| **Remark (If any) :** | | | | | |

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- Holding the applicator "B" in place, slowly and carefully push the inner plunger "A" as far as it will go so **the tablet is deposited into the vagina** (Diagram 3)

3




- Remove the disposable applicator from the vagina and dispose of it safely, out of the reach of children. The applicator cannot be flushed down the toilet.

Since the tablet dissolves in the vagina, it is quite common to notice a white chalky residue after using. This does not mean that the treatment has not worked. However, if you notice pieces of undissolved tablet, speak to your doctor or a pharmacist, as the treatment may not have worked properly.

**Duration of treatment**
- The symptoms of thrush should disappear within 3 days of treatment.
- If no improvement is seen after 7 days you must tell your doctor.
- If the infection returns after 7 days you may use one further treatment.
- If you have more than 2 infections within 6 months, you should see your doctor.

**If anyone accidentally swallows the tablet**
Clotrimazole **vaginal** tablets should **only be used in the vagina**.
**Do not put in your mouth or swallow it.**
If the vaginal tablet is swallowed accidentally, contact your doctor or nearest hospital emergency department **immediately** for advice. Remember to take this leaflet with you.

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

## 4. Possible side effects

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

**Seek medical advice immediately if you develop the following symptoms:**
- Allergic reactions: rash, swelling of the face, throat or tongue, difficulty in swallowing or breathing, weakness, dizziness, fainting, nausea

**After using Clotrimazole vaginal tablet, you might experience:**
- Vaginal peeling
- Severe itching (pruritus)
- Redness, rashes (erythema)
- Swelling of parts of the body (oedema)
- Discomfort, burning sensation, irritation or vulvovaginal pain
- Vaginal discharge or bleeding
- Stomach pain

**Reporting of side effects**
If you get any side effects, talk to your doctor or pharmacist. 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 or search for 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 medicinal product.

## 5. How to store Clotrimazole

- Keep this medicinal product out of the sight and reach of children.
- Do not use this medicinal product after the expiry date which is stated on the carton after "EXP". The expiry date refers to the last day of that month.
- Do not store above 25°C. Store in the original package in order to protect from moisture.
- After use, the disposable applicator is to be safely disposed of. It cannot be flushed down the toilet.

## 6. Contents of the pack and other information

**What Clotrimazole Vaginal Tablets contains:**
Each 500 mg **vaginal** tablet contains 500 mg Clotrimazole.

**The other ingredients are:**
Adipic acid, microcrystalline cellulose, pre-gelatinised maize starch, sodium hydrogen carbonate, stearic acid, lactose, polysorbate 80, magnesium stearate, maize starch, colloidal silicon dioxide

**What Clotrimazole Vaginal Tablets look like and the contents of the pack:**
Clotrimazole **vaginal** tablets are white, oblong uncoated **vaginal** tablets with "500" debossed on one side and plain on the other.

The pack contains 1 **vaginal** tablet with a disposable applicator.

**Marketing Authorisation Holder and Manufacturer:**
Tillomed Laboratories Limited
220 Butterfield, Great Marlings
Luton, LU2 8DL, United Kingdom

**Product Licence Number:** PL 11311/0042

This leaflet was last revised in March 2023

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