

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed without a doctor's prescription

Clothree

Vaginal tablets

Composition:

Each vaginal tablet contains:
clotrimazole 200 mg

For information about inactive ingredients, see section 6 - "Additional information".

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

Use the medicine according to the instructions provided in the dosage section of this leaflet.

Consult the pharmacist if you need further information.

Contact your doctor if disease symptoms worsen or do not improve after 7 days.

1. What is this medicine intended for?

- For treatment of vaginal fungal infections caused mainly by *Candida* species.
- For treatment of vaginal infections caused by trichomonas and microorganisms sensitive to clotrimazole.

Therapeutic group: antifungals from the azole family.

Vaginal candidiasis is a common infection from which most of the women suffer at a certain stage of life; it is not caused by impaired personal hygiene. Vaginal candidiasis is caused by a fungus called *Candida*, residing in the vagina and various organs without causing any damage. However, the natural balance that keeps *Candida* under control can be affected by several factors, such as hormonal changes (menstrual period, contraceptive pills, pregnancy, menopause), poor health, intake of antibiotics, fragranced soaps, bath additives and tight clothes.

Change in the natural acidity (pH) may lead to increased growth of the fungus, which may then develop into an infection.

This can be manifested by the following symptoms: persistent sensation of burning and/or itching around the vagina and vulva, redness, swelling and pain in the vaginal and vulvar tissues and white odorless vaginal discharge. You may not experience all of the symptoms listed above, but only one of them.

2. Before using this medicine:

Do not use this medicine if:

You are sensitive (allergic) to the active ingredient (clotrimazole) or to any of the other ingredients contained in the medicine (see section 6 "Additional information")

Special warnings about using this medicine

Use the medicine only if your doctor has previously diagnosed you with vaginal fungal infection.

Before treatment with Clothree, tell your doctor if:

- You are not sure whether you have vaginal fungal infection or this is the first time you experience these symptoms.
- You have suffered from a vaginal infection more than twice within the last 6 months.
- You or your partner have ever suffered from a sexually transmitted disease.
- You are below the age of 16 years or over the age of 60 years.
- You have ever experienced an allergic reaction to Clothree or to other vaginal antifungal medicines.
- If you have any of the following symptoms, Clothree may not be a suitable treatment for you:
 - irregular vaginal bleeding
 - unusual vaginal bleeding or bloody discharge
 - ulcers, blisters or sores in the vagina or vulva
 - lower abdominal pain
 - pain or difficulty in passing urine
 - fever or chills
 - nausea or vomiting
 - diarrhea
 - vaginal discharge with a bad odor
- Like other medicines for vaginal use, Clothree may reduce the effectiveness of contraceptives made of rubber, such as a condom and diaphragm. Therefore, you should use alternative contraceptives for at least 5 days after treatment with the medicine.
- Do not use tampons, vaginal douching preparations, spermicides or other vaginal preparations during treatment with this medicine.
- Refrain from vaginal sexual intercourse as long as you suffer from vaginal fungal infection or use Clothree, since the disease can be transmitted to your partner.

Girls and adolescents

Clothree vaginal tablets are not intended for use in girls and adolescents below the age of 12.

Drug interactions

If you are taking, or have recently taken, other medicines including non-prescription medicines and nutritional supplements, tell your doctor or pharmacist. Especially inform the doctor or pharmacist if you are taking:

- tacrolimus or sirolimus (intended to reduce the immune system response to prevent transplant rejection after organ transplantation).

Fertility, pregnancy and breastfeeding

Fertility

There is evidence indicating that the medicine has no effect on fertility.

Pregnancy

If you are pregnant or trying to become pregnant, consult your doctor or pharmacist before using Clothree and follow their instructions carefully. Clotrimazole may be used during pregnancy only under a doctor's supervision. Do not use the insertion device throughout the pregnancy period.

Breastfeeding

Since a risk to the nursing baby cannot be excluded, you should make a decision together with your doctor whether to breastfeed or to use clotrimazole.

Driving and using machines:

This medicine has no effect or a negligible effect on the ability to drive or operate machines.

3. How to use this medicine?

Check with your doctor or pharmacist if you are not sure about your dose or about how to use this medicine.

The recommended dosage, unless instructed otherwise by the doctor:

One tablet for vaginal insertion in the evening before bedtime, for 3 consecutive evenings (see "How to use the medicine").

Do not exceed the recommended dose.

Treatment duration

- The signs of candidiasis should resolve within 3 days of treatment initiation. If your condition does not improve within 7 days, contact your doctor.
- If candidiasis recurs after 7 days, you may receive one additional treatment, but if you suffer from candidiasis more than twice within 6 months, contact your doctor.

Mode of administration:

- Do not put in the mouth or swallow!
- For vaginal use only

How to use the medicine – general instructions:

If Clothree has been prescribed to you by your doctor, follow their instructions.

If you have purchased the medicine without a doctor's prescription, use the medicine as described in this section.

- The applicator enclosed with the medicine is intended to assist in inserting the tablet as deep as possible into the vagina, preferably before bedtime for **three consecutive evenings**.
- The applicator is personal (do not transfer it to another patient) and is intended for use during one treatment period of 3 days only.
- For hygiene maintenance, before each applicator use, wash its parts separately with water and soap.
- Wash your hands with soap and hot water before removing the tablet from the package, and again after using the special applicator.

1. Remove the applicator from the packaging. Pull out the inner part of the device (figure 1:a) until it stops. Remove the tablet from the foil packaging and place it in the wide part of the applicator (figure 1:b).
2. Insert the applicator containing the tablet as deep into the vagina as possible, without causing discomfort (The best way to do it is lying on your back with bent legs, and with your knees pointing upward). Hold the applicator in place and push the plunger slowly until it stops, so that the tablet is inserted into the vagina (see figure 2). Wait a few minutes before getting up.

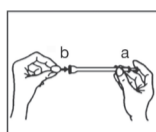


Figure No. 1

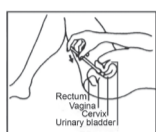


Figure No. 2

Figure No. 1

Pull the inner part of the applicator (a) outwards until it stops. Insert one vaginal tablet into the wide part of the applicator (b).

3. Remove the applicator. After each use, completely remove the plunger (A) from the applicator (B). Wash with hot (not boiling) water and soap and dry carefully.
4. After the end of the treatment period, discard the applicator in a safe place, out of the reach of children. Do not discard the applicator in the toilet.

- The vaginal tablet dissolves in the vagina, therefore it is advisable to wear a pad since white residues can be frequently observed after using the medicine. This does not indicate that the treatment has not worked adequately. But if you notice whole undissolved pieces of the tablet, the treatment may have been unsuccessful and you should contact your doctor or pharmacist.
- To prevent future recurrence: wear only cotton underwear that are not too tight and change them often. Take a shower every day. Wiping in the toilet should be performed from the front backwards. Refrain from wearing clothes that are too tight and nylon stockings. Refrain from bathing with fragranced soaps or using deodorants in the vaginal area. Do not rub the area firmly with a bath sponge. Refrain from hot baths with fragrance oils.

If you have accidentally used a higher dose, or if a child or someone else has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

If you forgot to use this medicine at the scheduled time:

- Use a dose as soon as you remember and continue with the remaining treatment normally.
- If you forgot for more than one day, the vaginal infection may not have been fully treated. Therefore, if the symptoms persist after the end of the treatment period, contact your doctor.

Do not take medicines in the dark! Check the label and dose every time you take a medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

Like with all medicines, using Clothree may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Side effects requiring special attention:

If you have sensitivity (allergy) to the medicine, an allergic reaction will occur soon after using the medicine. **Stop the treatment and contact the doctor or proceed to the emergency room of the nearest hospital immediately** if you develop an allergic reaction or experience worsening of redness, sensation of burning, pain, itching or worsening of swelling.

Signs indicating an allergic reaction include rash; problems swallowing or breathing; swelling of the lips, face, throat or tongue; weakness, dizziness or fainting; nausea.

Side effects that may occur after using the vaginal tablet:

- itching, redness, rash, swelling, discomfort, burning, irritation or peeling in the vaginal area or bleeding.
- pain in the abdomen or in the pelvic region.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor or pharmacist.

Reporting side effects

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link: <https://sideeffects.health.gov.il>

5. How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants.
- Do not induce vomiting unless explicitly instructed to do so by a doctor!
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.
- **Store below 25°C, do not freeze.**
- Do not throw away any medicine via wastewater or household waste. Ask the pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Additional information

In addition to the active ingredient, this medicine also contains:

Lactose monohydrate, microcrystalline cellulose, crospovidone, calcium lactate pentahydrate, povidone, lactic acid, magnesium stearate, silicon dioxide.

What the medicine looks like and contents of the pack:

Each pack contains 3 white to off white, bullet shaped tablets packed in a blister with an applicator (insertion device).

Manufacturer's and Registration Holder's name and address:

Teva Israel Ltd., 124 Dvora HaNevi'a St., Tel Aviv 6944020.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 127.41.30473

This leaflet was revised in May 2022 according to MOH guidelines