

**PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986**

The medicine is dispensed without a doctor's prescription

## Clothree

### Vaginal tablets

Composition:

Each vaginal tablet contains: clotrimazole 200 mg

For information about the inactive ingredients, please see section 6 'Further Information'.

**Read this package insert carefully in its entirety before using this medicine.** This leaflet contains concise information about the medicine. If you have further questions, consult your doctor or pharmacist. The medicine is intended for women 16 to 60 years of age.

Patients under 16 or over 60 years old must consult a doctor.

Use this medicine correctly.

Consult your pharmacist if you need more information.

Symptoms usually pass after 7 days of treatment.

Consult your doctor if your condition does not improve within 3 days.

### 1. WHAT IS THIS MEDICINE INTENDED FOR?

- vaginal infections caused by fungi, mainly *Candida* strains.
- vaginal infections caused by trichomonas and microorganisms sensitive to clotrimazole.

**Therapeutic group:** azole antifungal.

### 2. BEFORE USING THIS MEDICINE:

#### Do not use the medicine:

- If you are sensitive (allergic) to the active ingredient or to any of the other ingredients in this medicine or to other antifungal substances from the azole group.
- When you are menstruating, because this treatment may be less effective.
- Under the age of 12.

#### Special warnings regarding use of the medicine:

This medicine may reduce the effect of contraceptives made of rubber such as condoms or diaphragms made of latex. Therefore it is recommended to use an alternative contraceptive for at least 5 days after using this medicine. During treatment and while you have a fungal infection it is recommended to abstain from sexual intercourse because you might infect your partner.

Do not use tampons, vaginal douches, spermicides or other vaginal preparations while you are taking this treatment.

#### Before treatment with Clothree, tell the doctor if:

- You are sensitive to any food or medicine.
- You are not sure if you have a fungal infection, or if this is the first time you have these symptoms.
- You have suffered from a vaginal infection more than twice during the past 6 months.
- You or your partner have had sexually transmitted diseases in the past.
- You are under 16 or over 60 years old.
- You have had an allergic reaction in the past to clotrimazole or to other vaginal antifungal medicines.
- You have any of the following symptoms:
  - o irregular vaginal bleeding
  - o unusual vaginal bleeding or bloodstained vaginal discharge
  - o ulcers, blisters or sores in the vagina or vulva
  - o lower abdominal pain
  - o pain or difficulty when passing urine
  - o fever or chills
  - o nausea or vomiting
  - o diarrhea
  - o foul-smelling discharge from the vagina

In such cases Clothree vaginal tablets may not be the right treatment for you. The treatment must be finished before your period starts.

#### Other medicines and Clothree:

If you are taking, or have recently taken, other medicines, including non-prescription medicines and dietary supplements, tell the doctor or pharmacist. You should especially inform the doctor or pharmacist if you are taking:

a medicine called tacrolimus or a medicine called sirolimus (medicines which reduce the immune reaction in order to prevent rejection of an organ after transplantation).

#### Pregnancy and breastfeeding

- If you are pregnant or trying to become pregnant, or if you are breastfeeding, tell your doctor before you start using Clothree. If you have already told your doctor, follow the doctor's instructions carefully.

In case of an internal fungus, the doctor may recommend that you use the tablets without the applicator.

#### Girls and adolescents

Do not use this medicine under the age of 12.

### 3. HOW SHOULD YOU USE THE MEDICINE?

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

In the absence of other instructions from the doctor, the usual dosage is:

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

#### Do not exceed the recommended dose.

Do not put in your mouth or swallow! This medicine is for vaginal use only.

#### How to use the medicine:

How to insert the medicine:

First, wash your hands.

Use the special applicator.

Follow the detailed instructions.

If you are pregnant, check with your doctor whether you should use the applicators to insert the medicine.

1. Remove the applicator from the package. Pull out the inner part of the applicator (Figure 1a) until it stops. Remove the tablet from foil package and place it firmly in the wide part of the applicator (Figure 1b).
2. In the evening before bedtime, lie on your back with your legs bent and knees facing upwards. Using the applicator, insert the medicine into your vagina as deeply as you can without using force or creating discomfort (see Figure 2). Release the medicine by pushing in the plunger. Wait a few minutes before getting up.
3. Wash your hands and the applicator thoroughly with soap and warm water and dry the applicator after each use.

If the external genital area is also irritated and/or red,

apply a cream containing clotrimazole. Duration of treatment: three consecutive evenings. Consult your doctor if the signs of illness (symptoms) get worse or do not improve within 7 days.

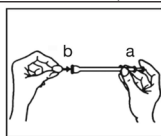


Figure 1



Figure 2

#### Figure 1

Pull out the inner part of the applicator (a) until it stops. Place one vaginal tablet in the wide part of the applicator (b).

If someone accidentally swallows the medicine, they must immediately contact the doctor or proceed to a hospital emergency room bringing the medicine package along, even if there is no discomfort or any sign of poisoning.

**If you forget to take this medicine** at the scheduled time, do not take a double dose. Take the next dose as soon as you remember. If you forgot for more than one day, the infection may not have been fully treated, so if the symptoms persist after the treatment period has ended, consult the doctor.

#### How can you contribute to the success of the treatment?

- Complete the treatment as prescribed.
- Do not engage in sexual intercourse or, alternatively, use a condom during sexual intercourse throughout the period of treatment because your partner could become infected. In addition, it is advisable to consult the doctor regarding the need for medicinal treatment for your partner as well.
- To make sure that the tablet comes into contact with moisture and dissolves completely it is important to insert it as deep as possible into the vagina.
- Wear only cotton underpants and change them frequently. Change your stockings every day as well.
- Do not use a vaginal douche during treatment with Clothree.
- When using a vaginal medicine underpants may become stained. To prevent staining, you can use a panty liner or sanitary pad.
- If you notice pieces of the tablet that did not dissolve, consult your doctor, since the treatment may not have worked properly.

If you are pregnant, consult your doctor before starting treatment.

- **Do not take medicine in the dark! Check the label and dose each time you use medicine. Wear glasses if you need them.**

**If you have further questions regarding use of the medicine, consult the doctor or pharmacist.**

### 4. Side effects

As with any medicine, use of 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:

As with all medicines, some people may be allergic to the tablets. If you are allergic, an allergic 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 medicine and see your doctor straight away or go immediately to the nearest emergency room.

Signs of allergic reaction: rash; problems with swallowing or breathing; swelling of the lips, face, throat or tongue; weakness, dizziness or fainting; nausea. If you experience these signs, stop the treatment and consult a doctor immediately.

Other side effects after starting treatment: itching, redness, rash, swelling, discomfort, burning, irritation or peeling of vaginal skin, bleeding, stomach or pelvic pain.

**If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, or if there is a change in your general feeling, consult your doctor or pharmacist immediately.**

#### Reporting side effects

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Medication' on the Ministry of Health home page ([www.health.gov.il](http://www.health.gov.il)) which links to an online form for reporting side effects. You can also use this link:

<https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il>

### 5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine must be kept in a close place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) stated on the package. The expiry date refers to the last day of that month.
- **Store below 25°C, do not freeze.**
- Do not discard medicines in the sink or in the trash. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help protect the environment. Do not discard the applicator in the toilet.

### 6. FURTHER 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 package:**

Each pack contains 3 creamy-white vaginal tablets packaged in a blister tray and an applicator (a device for inserting the tablet).

**Manufacturer and license holder's name and address:** Teva Pharmaceutical Industries Ltd., P.O.B. 3190, Petach Tikva.

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

This leaflet was reviewed and approved by the Ministry of Health in March 2013 and revised in December 2018 in accordance with Ministry of Health guidelines.

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