

## **Package leaflet: Information for the patient**

### **Clotrimazole 500mg Vaginal Tablets**

Clotrimazole

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet:**

1. What Clotrimazole 500mg Vaginal tablets are and what they are used for
2. What you need to know before you use Clotrimazole 500mg Vaginal tablets
3. How to use Clotrimazole 500mg Vaginal tablets
4. Possible side effects
5. How to store Clotrimazole 500mg Vaginal tablets
6. Contents of the pack and other information

#### **1. What Clotrimazole 500mg Vaginal tablets are and what are they used for**

Clotrimazole 500mg Vaginal tablets contain the active substance clotrimazole which belongs to a group of medicines called imidazoles, which are used to treat fungal infections.

Clotrimazole 500mg Vaginal tablet is a single course of treatment for the vaginal thrush. It is inserted into the vagina for treatment at the site of infection (see section 3, “How to use Clotrimazole 500mg Vaginal tablets”). A second treatment may be carried out, if necessary.

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 500mg Vaginal tablets**

### **Do not use Clotrimazole 500mg Vaginal tablet:**

- If you are allergic (hypersensitive) to clotrimazole or any of the other ingredients of Clotrimazole 500mg Vaginal tablet (see Section 6. Further Information).
- During your period as it may be less effective.

### **Before using Clotrimazole 500mg Vaginal tablet, 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 500mg Vaginal tablets 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 500mg Vaginal tablet may not be the right treatment for you.

### **Warnings and precautions:**

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.

Do not use tampons, intravaginal douches, 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 500mg Vaginal tablets**

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**

If you are pregnant, breast-feeding or trying for a baby, tell your doctor or midwife before using Clotrimazole 500mg Vaginal tablets. If you have informed your doctor or midwife already, follow his/her instructions carefully.

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

### **3. How to use Clotrimazole 500mg Vaginal tablets**

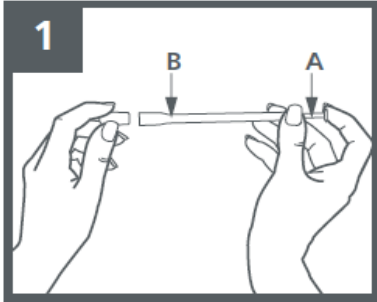
If Clotrimazole 500mg Vaginal tablet has been prescribed for you by your doctor, follow any instructions he/she may have given you. If you purchased this product without a prescription, follow these directions closely:

The applicator should be used to insert the tablet as high as possible into the vagina, preferably before going to sleep at night for convenient and comfortable treatment.

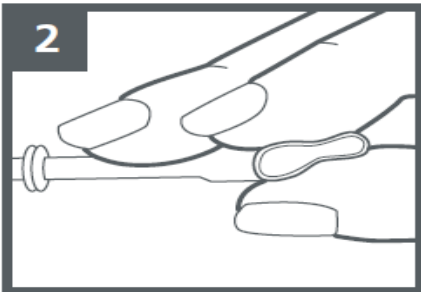
Wash your hands before removing the foil from the blister pack and again afterwards when you have used the applicator.

#### ***Instructions how to insert Clotrimazole 500mg Vaginal Tablet***

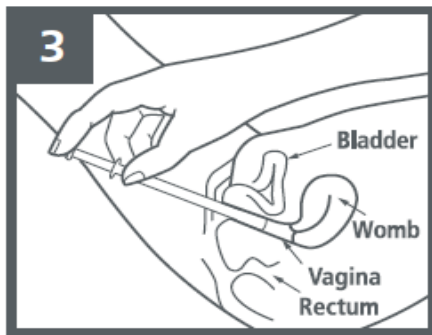
1. Remove the applicator from the packaging. Pull out the plunger A until it stops. Remove the tablet from the blister pack and place firmly into the applicator B.



2. To fit the tablet into the applicator, the holder of the applicator needs to be squeezed lightly at both sides. The tablet fits tightly into the applicator and needs to be squeezed into the holder to about 1cm.



3. Carefully insert the applicator into the vagina as deeply as is comfortable. This is easiest done when lying on your back with your legs slightly bent. Holding the applicator in place, slowly press the plunger until it stops so that the tablet is deposited into the vagina.



4. Remove the applicator. Dispose of the applicator in a safe place, out of the reach of children. The applicator cannot be flushed down the toilet.

Since the tablet dissolves in the vagina, it may be helpful to wear a panty liner because it is quite common to notice a white chalky residue after using the tablet. 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.

The symptoms of thrush should disappear within three days of treatment. If no improvement is seen after seven days, you must tell your doctor. If the infection returns after seven days you may use one further treatment, but if you have more than two infections within six months you should see your doctor.

**Clotrimazole 500mg Vaginal tablet is for use in the vagina only:**

Do not put the tablet in your mouth or swallow it.

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

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, Clotrimazole 500mg Vaginal tablet can cause side effects, although not everybody gets them.

As with all medicines, some people may be allergic to the pessary. 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 use Clotrimazole 500mg Vaginal tablet you might experience:

- Itching, rash, swelling, redness, discomfort, burning, irritation, vaginal peeling or bleeding.
- Pain in the abdomen or pelvic area.

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 Clotrimazole 500mg Vaginal tablets**

- Keep out of the sight and reach of children.
- Do not use after the expiry date which is stated on the container label and on the carton. 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.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment

### **6. Contents of the pack and other information**

#### **What Clotrimazole 500mg Vaginal Tablets contain**

Each 500mg vaginal tablet contains 500mg clotrimazole.

The other ingredients are: adipic acid, pregelatinised maize starch, maize starch, microcrystalline cellulose, sodium hydrogen carbonate, magnesium stearate, stearic acid, colloidal silicon dioxide and polysorbate 80.

#### **What Clotrimazole 500mg Vaginal Tablets look like and contents of the pack**

Clotrimazole 500mg vaginal tablets are white colored, oblong shaped uncoated tablets having "500" debossed on one side and plain on the other side.

The pack contains 1 vaginal tablet with a disposable applicator.

**Marketing Authorisation Holder and Manufacturer**

Marketing Authorisation Holder

RxFarma, Colonial Way, Watford,  
WD24 4YR, United Kingdom

Manufacturer

Rx Farma Limited,  
Units 1-7, Colonial Way,  
Watford, Hertfordshire, WD24 4YR

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