PACKAGE LEAFLET – INFORMATION FOR THE USER CLOTRIMAZOLE 500MG VAGINAL TABLETS

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 or your pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects, talk to you doctor or pharmacist. This includes any possible side effects not listed in the leaflet.

What is in this leaflet:

- 1. What Clotrimazole 500mg Vaginal Tablet is and what it is 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 Tablet is what it is used for

Clotrimazole 500mg Vaginal Tablet is a full course of treatment for vaginal thrush (candidiasis). It is inserted into the vagina for treatment at the site of infection.

The active substance in Clotrimazole 500mg Vaginal Tablets is clotrimazole. It belongs to a group of medicines called azoles and is an antifungal agent which fights the cause of infections such as vaginal thrush.

2. What you need to know before you use Clotrimazole 500mg Vaginal Tablets Do not use Clotrimazole 500mg Vaginal Tablets if you:

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

Special precautions:

As with other pessaries, 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

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

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

Pregnancy, breast-feeding and fertility

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 vaginal tablet without the help of an applicator.

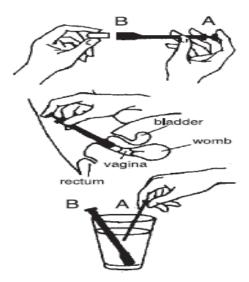
Driving and using machines

The medication has no or negligible influence on the ability to drive or use machinery.

3. How to use Clotrimazole 500mg Vaginal Tablets

- 1. Pull out plunger A until it stops. Place one vaginal Tablet into the applicator B
- 2. Insert applicator containing the tablet carefully as deep as possible into the vagina (this is done best by lying on back)
- 3. Push plunger A until it stops, thereby depositing the tablet into the vagina. Withdraw the applicator.
- 4. After use, remove plunger A completely by pulling out of the applicator B. Thereafter wash both in warm (not boiling) soapy water and dry completely.

The symptoms of thrush should disappear within three days of treatment. If no improvement is seen after seven days you must tell your doctor.



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

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

If the pessary 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, Clotrimazole 500mg Vaginal Tablets can cause side effects, although not everybody gets them.

As with all medicines, some people may be allergic to the vaginal tablet. 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 the 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 immediately.

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

5. How to store Clotrimazole 500mg Vaginal Tablets

Store below 30°C. Protect from moisture and light

6. Contents of the pack and other information

A printed carton containing a leaflet, an applicator packed in polypropylene bag and a printed aluminium strip containing 1 white biconvex vaginal uncoated tablet with G logo on one side and plain on other side

This leaflet was last revised in Aug 2020.