| | |
|---|---|
| **Applicant Name: Glenmark Pharmaceuticals (Pty) Ltd**<br>**Proprietary Name: Glenmark Clotrimazole 1 Vaginal Tablet**<br>**Glenmark Clotrimazole 6 Vaginal Tablet**<br>**Dosage form: Vaginal Tablet** | |

**PATIENT INFORMATION LEAFLET**

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

GLENMARK CLOTRIMAZOLE 1 VAGINAL TABLET and GLENMARK CLOTRIMAZOLE 6 VAGINAL TABLET is available without a doctor's prescription, for you to treat a mild illness. Nevertheless you still need to use GLENMARK CLOTRIMAZOLE 1 VAGINAL and GLENMARK CLOTRIMAZOLE 6 VAGINAL carefully to get the best result from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.

You must see a doctor if your symptoms worsen or do not improve

**SCHEDULING STATUS OF THE MEDICINAL PRODUCT**

S1

**NAME OF THE MEDICINAL PRODUCT**

GLENMARK CLOTRIMAZOLE 1 VAGINALTABLET

GLENMARK CLOTRIMAZOLE 6 VAGINAL TABLET

**WHAT GLENMARK CLOTRIMAZOLE 1 VAGINALTABLET AND GLENMARK CLOTRIMAZOLE 6 VAGINAL TABLET CONTAINS**

GLENMARK CLOTRIMAZOLE 1 VAGINALTABLET:

Each tablet contains 500 mg clotrimazole as the active ingredient.

GLENMARK CLOTRIMAZ0LE 6 VAGINAL TABLET:

Each tablet contains 100 mg clotrimazole as the active ingredient.

Preservatives included:

Propylparaben 0,02 % w/w

Methylparaben 0,08 % w/w

Other ingredients included are: lactose, maize starch, sodium starch glycollate, povidone, purified talc, magnesium stearate, colloidal silicon dioxide, adipic acid, sodium bicarbonate.

**WHAT GLENMARK CLOTRIMAZOLE VAGINALTABLET IS USED FOR**

For the treatment and relief of vaginal itching, burning and discharge caused by fungal infections (vaginal candidiasis).

**BEFORE YOU USE GLENMARK CLOTRIMAZOLE VAGINALTABLET**

**Do not use GLENMARK CLOTRIMAZOLE VAGINALTABLET:**

If you are allergic to clotrimazole or any of the ingredients contained in GLENMARK CLOTRIMAZOLE VAGINAL TABLET.

**Take special care with GLENMARK CLOTRIMAZOLE VAGINAL TABLET:**

I. GLENMARK CLOTRIMAZOLE VAGINAL TABLET should not be taken by mouth but should be inserted into the vagina.

II. Use only if you have already had a vaginal yeast infection diagnosed by a medical practitioner and you have the same symptoms now, otherwise consult your doctor. These symptoms include itching and burning of the vagina and sometimes a white discharge.

III. If there is no improvement in 3 days or if symptoms have not disappeared in 7 days, then consult a medical practitioner as not all vaginal infections are caused by yeasts.

IV. Consult a medical practitioner if you have abdominal pain, fever or a foul-smelling vaginal discharge before or during the use of this medication.

V. If symptoms recur within 2 months, consult a medical practitioner.

VI. If you are pregnant or think you may be pregnant or nursing/breastfeeding, do not use this medication except on the advice of a medical practitioner.

VII. Do not use in girls under 12 years of age, except on the advice of a medical practitioner.

VIII. If skin rash or new irritation occurs, discontinue the use of GLENMARK CLOTRIMAZOLE VAGINAL TABLET.

**Pregnancy and Breastfeeding:**

If you are pregnant or think you may be pregnant or are nursing / breastfeeding, do not use GLENMARK CLOTRIMAZOLE VAGINAL TABLET except on the advice of a medical practitioner.

GLENMARK CLOTRIMAZOLE VAGINAL TABLET should not be administered to pregnant women, since the safety in this regard has not been established.

**Taking other medicines with GLENMARK CLOTRIMAZOLE VAGINAL TABLET:**

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of GLENMARK CLOTRIMAZOLE VAGINAL TABLET with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional, for advice.

**HOW TO USE GLENMARK CLOTRIMAZOLE VAGINAL TABLET**

Check which product the doctor, pharmacist or healthcare professional has supplied you with and follow the instructions under the respective heading.

GLENMARK CLOTRIMAZOLE 1 VAGINALTABLET:

Insert one tablet as deeply into the vagina as possible with the aid of the applicator supplied in the pack, preferably before going to bed.

GLENMARK CLOTRIMAZOLE 6 VAGINALTABLET:

Insert one tablet daily into the vagina, preferably before going to bed. This should be continued for 6 consecutive days. The tablet is to be inserted as deeply into the vagina as possible with the aid of the applicator supplied in the pack. It is best to use the vaginal tablets when you are not menstruating/having your periods.

For prevention of re-infection your partner should be treated locally with clotrimazole cream at the same time.

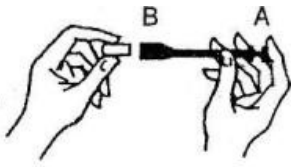
Directions for using the Applicator:

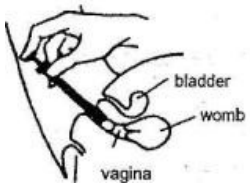
Prior to application remove the tablet from the aluminium foil.

1. Pull out plunger A until it stops. Place the vaginal tablet into the applicator B.

2. Insert applicator containing the tablet carefully and as deeply as possible into the vagina (this is done best by lying on your back).

3. Push the plunger A until it stops, thereby depositing the tablet into the vagina. Remove the applicator



Important notice

Pregnant women should follow the instructions of their doctor strictly. During pregnancy insertion should be done without using the applicator.

**POSSIBLE SIDE EFFECTS**

GLENMARK CLOTRIMAZOLE VAGINAL TABLET can have side effects

Skin Around Vagina:

Frequent:

- Local reactions including irritation and burning may occur.
- Skin rash (contact allergic dermatitis).

In the case of systemic absorption, the following side effects have been reported and the frequencies are unknown:

- Lower abdominal cramps
- Nausea or diarrhoea caused by a hypersensitivity reaction.
- Increase in urinary frequency
- Shortness of breath due to a hypersensitivity reaction.
- Decrease in blood pressure and impaired consciousness as a result of a hypersensitivity reaction.
- Skin rash may occur (e.g. itching, redness) due to a hypersensitivity reaction

Not all side effects reported for GLENMARK CLOTRIMAZOLE 1 VAGINAL TABLET and GLENMARK CLOTRIMAZOLE 6 VAGINAL TABLET are included in this leaflet. Should your general health worsen while taking GLENMARK CLOTRIMAZOLE 1 VAGINAL TABLET or GLENMARK CLOTRIMAZOLE 6 VAGINAL TABLET**,** please consult your doctor, pharmacist or other health care professional for advice.

**STORING AND DISPOSING OF GLENMARK CLOTRIMAZOLE VAGINAL TABLET**

Store in a cool, dry place at or below 25 °C. Protect from moisture and light.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets)

**KEEP ALL MEDICINES OUT OF REACH OF CHILDREN**

**PRESENTATION**

GLENMARK CLOTRIMAZOLE1 VAGINALTABLET:

Carton containing a single tablet sealed into an aluminium/aluminium blister. The carton also contains a specially designed applicator.

GLENMARK CLOTRIMAZOLE 6 VAGINAL TABLET:

Carton containing six individually sealed tablets into an aluminium/aluminium blister. The carton also contains six specially designed applicators.

**IDENTIFICATION**

GLENMARK CLOTRIMAZOLE 1 VAGINAL TABLET:

White, biconvex, vaginal, uncoated tablet, with "G" logo on one side and plain on the other side.

GLENMARK CLOTRIMAZOLE 6 VAGINAL TABLET:

White, biconvex, vaginal, uncoated tablet, with "G" logo on one side and "V6" on the other side.

**REGISTRATION NUMBERS**

GLENMARK CLOTRIMAZOLE 1 VAGINAL TABLET: 32/20.2.2/0042

GLENMARK CLOTRIMAZOLE 6 VAGINAL TABLET: 32/20.2.2/0041

**NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION**

Glenmark Pharmaceuticals South Africa (Pty) Ltd

Unit 7/8 York House

Tybalt Place, 185 Howick Close

Waterfall Office Park, Bekker Street

Vorna Valley, Midrand

Tel: 011 564 3900

**DATE OF PUBLICATION**

2 March 2012