

PATIENT INFORMATION LEAFLET

Clotrimazole 500mg Vaginal Tablet

(Clotrimazole)

Read all of this leaflet carefully before you start using this medicinal product because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicinal product 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

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1 What Clotrimazole is and what it is used for

This medicinal product contains 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 **vaginal** thrush (candidal vaginitis). It is inserted into the vagina for treatment at the site of infection (see section 3, "How to use Clotrimazole").

Thrush is a common infection and is caused by a yeast (fungus) which lives harmlessly in the vagina without you even noticing it. However, the natural pH balance that keeps the yeast under control may become disrupted due to factors such as hormonal changes. This can cause the level of yeast to increase and develop into an infection in the vagina and the surrounding area (vulva).

Symptoms of thrush may include the following:

- Persistent burning and/or itching around the vagina and vulva
- Redness, swelling and soreness of the vagina and vulva
- A white non-smelling discharge from the vagina

2 What you need to know before you use Clotrimazole

Do not use Clotrimazole if:

- You are allergic (hypersensitive) to Clotrimazole, imidazoles, other vaginal anti-fungal products or any of the other ingredients of this medicinal product (See Section 6 "Contents of the pack and other information")
- You suffer from any of the following symptoms:
 - Irregular vaginal bleeding
 - Abnormal vaginal bleeding or a blood-stained discharge
 - Vulval or vaginal ulcers, blisters or sores
 - Lower abdominal pain
 - Pain when passing urine (dysuria)
 - Any adverse events such as redness, irritation or swelling associated with the treatment
 - Fever or chills
 - Feeling sick (nausea) or being sick (vomiting)
 - Diarrhoea
 - Foul-smelling vaginal discharge

Warnings and precautions

Talk to your doctor before using Clotrimazole:

- If this is first time you have experienced symptoms of thrush
- If you have had more than 2 infections of thrush in the last 6 months
- If you have a previous history of sexually transmitted disease or have been exposed to a sexually transmitted disease
- If you are or suspect you are pregnant (see "Pregnancy" section)
- If you are aged under 16 or over 60 years of age

Other medicines and Clotrimazole

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.

Medicines which **may interact** with Clotrimazole:

- Other medicines used to treat fungal infections such as amphotericin and nystatin (polyene antibiotics)
- Medicines used to reduce the body's immunity when receiving organ transplant such as tacrolimus (immunosuppressants)

Pregnancy and Breast-feeding

Pregnancy

You must tell your doctor if you are pregnant or if you think that you are.

Clotrimazole can be used during pregnancy but only under the supervision of a doctor or midwife. If your doctor tells you that you can use Clotrimazole during pregnancy, the vaginal tablet can be inserted without using the applicator.

Breast-feeding

Tell your doctor if you are breast-feeding or about to start breast-feeding. A risk to the suckling child cannot be excluded and your doctor will decide whether or not you should continue breast-feeding taking into account the benefit of breast-feeding for the child and the benefit of treatment for you.

Clotrimazole contains lactose

If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before using this medicinal product.

3 How to use Clotrimazole

Always use this medicinal product exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

- Treatment consists of one **vaginal** tablet, which should be inserted **into the vagina** at night.
- Do not use this product if you are on your period. Start the treatment once your period has finished.
- Although best avoided, you may continue to have sexual intercourse during treatment unless your doctor has advised you not to. However, this product may cause damage to latex contraceptives (e.g. condoms or diaphragms) and consequently may reduce the effectiveness of such contraceptives. You should use alternative contraception for at least 5 days after using this product.
- Do not use tampons, douches (vaginal washes/cleansers) or other vaginal products whilst using this product.

Instructions how to insert Clotrimazole Vaginal Tablet

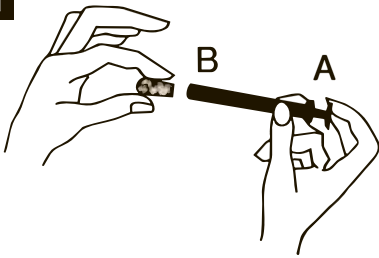
- Wash your hands before and after inserting the **vaginal** tablet
- Remove the applicator from the packaging

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Hard to Read? Phone 0800 970 6115 for help

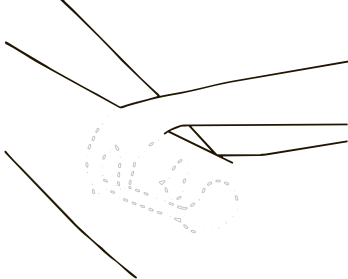
- Remove the tablet from the aluminium package and place it firmly into the open end of the disposable applicator "B" (Diagram 1)
- To fit the tablet into the applicator, squeeze the applicator lightly on both sides, whilst pushing the tablet far enough into the holder (about 1 cm) to be held in place during insertion

1



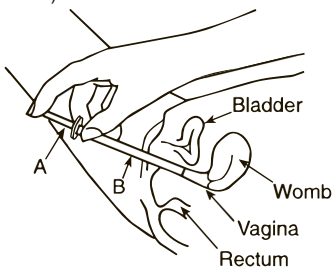
- Carefully insert the applicator into the vagina as deeply as is comfortable. This is easiest done when lying on your back with your legs slightly bent (Diagram 2)

2



- Holding the applicator "B" in place, slowly and carefully push the inner plunger "A" as far as it will go so **the tablet is placed in the vagina** (Diagram 3)

3



- Remove the disposable applicator from the vagina and dispose of it in a safe place, out of the reach of children. The applicator cannot be flushed down the toilet.

Duration of treatment

- Each course of treatment consists of one Clotrimazole **vaginal** tablet, which remains effective for 3 days.
- After 1-2 days, most of the external symptoms of the infection (e.g. discharge, itching etc) should have disappeared.
- If the symptoms have not been relieved or if the infection returns within 7 days of using Clotrimazole **vaginal** tablet, treatment may be repeated.
- If the infection recurs more than twice within 6 months, you should consult your doctor.

If anyone accidentally swallows the tablet

Clotrimazole **vaginal** tablets should **only be used in the vagina**.

If you or anyone else has accidentally swallowed the vaginal tablet, you must contact your doctor or nearest emergency department **immediately** for advice. Remember to take this leaflet with you.

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, this medicinal product can cause side effects, although not everybody gets them.

Seek medical advice immediately if you develop the following symptoms:

- Allergic reactions: swelling of the face, throat or tongue, fever, difficulty in breathing, dizziness (this may also include fainting, low blood pressure, skin rashes with or without the formation of wheals)
- Intolerable burning sensation or irritation

Side effects (frequency not known)

- Mild burning or irritation immediately after inserting the **vaginal** tablet
- Peeling of the genitals
- Severe itching (pruritus)
- Rashes (erythema)
- Swelling of parts of the body (oedema)
- Discomfort, burning sensation, irritation or pelvic pain
- Vaginal bleeding
- Stomach pain

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. You can also report side effects directly via the internet at (www.mhra.gov.uk/yellowcard). By reporting side effects you can help provide more information on the safety of this medicinal product.

5 How to store

- Keep this medicinal product out of the sight and reach of children.
- Do not use this medicinal product after the expiry date which is stated on the container after "EXP". 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.

6 Contents of the pack and other information

What Clotrimazole Vaginal Tablets contains:

Each 500mg **vaginal** tablet contains 500mg Clotrimazole.

The other ingredients are:

Adipic acid, microcrystalline cellulose, pre-gelatinised maize starch, sodium hydrogen carbonate, stearic acid, lactose, polysorbate 80, magnesium stearate, maize starch, colloidal silicon dioxide

What Clotrimazole Vaginal Tablets look like and the contents of the pack:

Clotrimazole **vaginal** tablets are white, oblong uncoated **vaginal** tablets with "500" embossed on one side and plain on the other. The pack contains 1 **vaginal** tablet with a disposable applicator.

Marketing Authorisation Holder and Manufacturer:

Tillomed Laboratories Ltd.
220 Butterfield, Great Marlings,
Luton, LU2 8DL,
UK

Product Licence Number:

PL 11311/0042



This leaflet was last revised in May 2018

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Product Name	Tillomed Clotrimazole
Strength / Form	500mg Tablet
Type	PIL
Dimensions	160 x 300 mm
Typefaces	Font SansSerif - Min. Text 8pt
Rev #	Till-Ver.6
Last updated	08/05/2018
No. of Colours	Pantone Black CVC