
Information for the user



Thrush 500 mg Vaginal Tablet (Clotrimazole)

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

This medicine is available without prescription to treat thrush. However, you still need to use it carefully to get the best results from it.

- Keep this leaflet, you may need to read it again
- Ask your pharmacist if you need more information or advice
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet
- You must talk to a doctor if you do not feel better or if you feel worse after 3 days

What this medicine is for

This pessary (also known as a “vaginal tablet”) contains Clotrimazole which belongs to a group of medicines called anti-fungals, which act to treat infections caused by fungi. It can be used to treat thrush (vaginal candidiasis). Thrush is a common infection caused by a yeast (or fungus), which may live harmlessly in the vagina without you even noticing it. However, in certain circumstances, it may develop into an infection in the vagina and symptoms may spread to the surrounding area. These symptoms may include one or more of the following:

- Itching of the vagina and surrounding area (the vulva)
- Redness and swelling of the tissues of the vagina and vulva
- Soreness of the vagina and vulva
- A white non-smelling discharge from the vagina

Thrush may be aggravated by sexual intercourse, but it is not a sexually transmitted disease. Sometimes however, thrush can be passed to your partner through sexual intercourse. If your partner has penile thrush he may have one or more of the following symptoms:

- Soreness and redness of the penis
- Tightness of the foreskin
- A white non-smelling penile discharge

Before you use this medicine

This medicine can be used by women between the ages of 16 and 60 years. However, some people should not use this medicine or should seek the advice of their pharmacist or doctor first.

X Do not use:

- **If you are allergic** to clotrimazole or any of the ingredients in this medicine (see “What is in this medicine”)
- **If you have an intolerance to some sugars**, unless your doctor tells you to (this medicine contains lactose)
- **During your period.** Wait until your period has finished

! Talk to your pharmacist or doctor:

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- If this is the first time you have had these symptoms
 - If you have had thrush more than twice in the last 6 months
 - If you are under 16 years, or 61 years or older
 - If you are allergic to imidazoles or any other antifungal medicines, including those applied into the vagina
 - If you or your partner have been exposed to a sexually transmitted disease
 - If you have lower stomach pain, or pain or a burning sensation on passing urine
 - If you have abnormal or irregular vaginal bleeding, or a blood-stained discharge
 - If you have foul smelling discharge
 - If you have sores, ulcers or blisters on your vulva or vagina
 - If you have fever or chills, you are feeling sick or being sick
 - If you have diarrhoea
 - If you are pregnant, or think you may be pregnant (see "Other important information")
 - If you are breastfeeding

Other important information

Pregnancy: This medicine may be used under the supervision of a doctor or midwife during pregnancy. If your doctor or midwife tells you that you can use this medicine, it should be inserted without the applicator.

Women of childbearing age: The ingredients in the pessary may affect the latex used in contraceptives such as condoms and diaphragms.

This may reduce the effectiveness of the contraceptives. You should therefore use other methods of contraception for at least 5 days after using the pessary.

You can help the treatment to work if you follow these simple self-help tips:

- Although the infected area will itch, do not scratch as this will damage the surface of the skin and cause the infection to spread further
- Keep the affected areas of skin clean
- Pay particular attention to drying the skin but avoid excessive rubbing

To help prevent thrush from coming back once you have treated it, follow these simple steps:

- Wash daily
- Wear cotton underwear and loose fitting clothing
- Try to avoid wearing tights, nylon underwear and tight fitting clothing
- After going to the toilet, wipe yourself from the front to the back, as a thrush infection may be transferred from the bowel
- Try to avoid washing with perfumed soaps or using vaginal deodorants
- Do not rub hard with sponges or flannels and avoid hot baths with strong perfumed oils
- Change your sanitary protection regularly

If you take other medicines

Before you use this medicine, make sure that you tell your pharmacist about ANY other medicines you might be using at the same time, particularly if you are taking the following:

- Amphotericin, or other antifungal medicines (e.g. nystatin)
- Tacrolimus or sirolimus (given after transplant surgery, or for psoriasis or rheumatism)

If you are unsure about interactions with any other medicines, talk to your pharmacist. This includes medicines prescribed by your doctor and medicine you have bought for yourself, including herbal and homeopathic remedies.

✓ How to use this medicine

The carton contains a single pessary held inside a foil blister pack and an applicator for insertion of the pessary into the vagina. Check the foil is not broken before use. If it is, do not use the pessary.

Women aged 16 to 60 years: Insert the pessary into the vagina at night using the applicator provided.

If you are pregnant do not use the applicator. Wash and dry your hands, and insert the pessary with your fingers.

Directions for inserting the pessary

- Wash your hands before use
- Remove the applicator from the packaging
- Pull out the plunger 'A' until it stops
- Remove the pessary from the blister pack and place the pessary firmly into the applicator 'B'
- To fit the pessary into the applicator, squeeze the applicator lightly on either side. The pessary fits tightly into the applicator and needs to be pushed into the holder about 1 cm
- Carefully put the applicator as deep as is comfortable into the vagina (this is easiest when laying on your back with your knees bent up)
- Holding the applicator in place, slowly press the plunger until it stops so that the pessary is deposited into the vagina. 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
- Wash your hands thoroughly after use

The pessary is for use in the vagina only. Do not swallow it.

Do not use tampons or other vaginal products whilst using this pessary.

Do not use for children under 16 years, or if you are an adult of 61 years or older, unless your doctor tells you to.

Do not use more than one pessary.

After you use this pessary, external symptoms of thrush (e.g. itching, discharge) should improve within 3 days.

If external symptoms have not improved within 3 days, or symptoms worsen, talk to your doctor.

If internal symptoms (e.g. discomfort and soreness) do not go away within 7 days, talk to your doctor.

If symptoms clear up and then return after 7 days, you can use another pessary.

If you have thrush more than twice in six months you must see a doctor.

- ! **If anyone accidentally swallows the pessary:** Talk to a doctor straight away or go to your nearest hospital casualty department. Take your medicine and this leaflet with you.

Possible side effects

Most people will not have problems, but some may get some.

- ! **If you get any of these serious side effect, see a doctor at once:**

- Difficulty in breathing, swelling of the face, neck, tongue or throat, low blood pressure, fainting (severe allergic reactions)
- Red, raised itchy skin rash, which may include peeling of the skin
- Intolerable irritation or burning sensation after inserting the pessary

If you get any of the following side effects see your pharmacist or doctor:

- Mild burning or irritation straight after inserting the pessary
- Other allergic skin reactions such as a rash, swelling of the vagina, vulva, discomfort

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- Lower stomach pain, pain in the pelvic area
 - Vaginal bleeding

The side effects of this medicine can be very similar to the symptoms that you are treating.

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

How to store this medicine

Do not store above 25°C.

Store in the original package in order to protect from moisture.

Keep this medicine in a safe place out of the sight and reach of children, preferably in a locked cupboard.

Use by the date on the end flap of the carton.

What is in this medicine

This vaginal tablet contains Clotrimazole 500 mg, which is the active ingredient.

As well as the active ingredient, the vaginal tablet also contains also contains adipic acid, microcrystalline cellulose, pregelantised maize starch, sodium hydrogen carbonate, stearic acid, lactose, polysorbate 80, magnesium stearate, maize starch, colloidal silicon dioxide.

The pack contains 1 vaginal tablet with an applicator. The vaginal tablet is white, oblong and uncoated with '500' embossed on one side and plain on the other.

Who makes this medicine

Manufactured for The Boots Company PLC Nottingham NG2 3AA,

Marketing Authorisation Holder and Manufacturer:

Tillomed Laboratories Ltd

3 Howard Road

Eaton Socon

St Neots

Cambridgeshire PE19 8ET

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If you would like any further information about this medicine, please contact The Boots Company PLC Nottingham NG2 3AA

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