

Information for the user



Thrush 150 mg Capsule (Fluconazole)

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

This medicine is available without prescription to treat thrush. However, you still need to take 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

What this medicine is for

This medicine contains Fluconazole, which belongs to a group of medicines called anti-fungals. These act to treat infections caused by fungi.

The medicine can be used to treat thrush (vaginal candidiasis). It may also be used by the woman's sexual partner to treat associated penile thrush (candidal balanitis).

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. The 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 take this medicine

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

X Do not take:

- **If you are allergic** to any of the ingredients or any other anti-fungal medicine (you may have difficulty breathing, swelling of the face, lips, tongue or throat, redness, irritation or swelling of the skin after taking this type of medicine in the past)

If you are taking any of these medicines:

- Terfenadine or astemizole (for allergy)
- Pimozide (for mental health conditions)
- Cisapride (for stomach problems)
- Quinidine (for heart rhythm problems)
- Erythromycin (for bacterial infections)
- Halofantrine (for treatment of malaria)

- **If you are suffering** from *Tinea Capitis* (fungal infection of the scalp)
- **If you have an intolerance to some sugars**, unless your doctor tells you to (this medicine contains lactose)
- **If you are pregnant, think you are pregnant, or you are breastfeeding** (see “Other important information”)

! Talk to your pharmacist or doctor:

- 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 or your partner have been exposed to a sexually transmitted disease
- If you have liver disease, or have had unexplained jaundice (yellowing of the skin and eyes)
- If you have kidney problems
- If you have heart problems, or low levels of potassium, magnesium or calcium in your blood
- If you have AIDS (you may be more likely to experience skin reactions)
- If you have any other long-term illness, or receive regular treatment from your doctor
- If you are taking any other medicines, except for the contraceptive “pill” (see “If you take other medicines” on the back of the leaflet)
- If you are unsure about the cause of your symptoms
- If you are a man and:
 - Your sexual partner **does not** have thrush
 - You have pain on passing urine
 - You have an abnormal discharge or leakage from your penis
 - You have sores, ulcers or blisters on your penis
 - Your penis has started to smell
- If you are a woman and:
 - You have lower stomach pain, or pain or a burning sensation on passing urine
 - You have any abnormal or irregular bleeding, or a blood stained discharge
 - You have sores, ulcers or blisters on your vulva or vagina

Other important information

Pregnancy: This medicine should not be used if you are pregnant, or if you think you may be pregnant.

Breastfeeding: This medicine should not be used if you are breastfeeding.

Driving and using machines: This medicine is not expected to affect your ability to drive or use machines. However, the medicine may cause dizziness and occasionally fits or other side effects that may affect you. You should not drive or use machines until you are sure you are not affected.

Treating thrush: 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

Information about some of the ingredients:

- E216 and E218 in this medicine may cause allergic reactions (possibly delayed).

Information on sodium content:

- Fluconazole capsules contain less than 1 mmol sodium (23mg) per tablet, that is to say essentially 'sodium-free'

If you take other medicines

Do not take this medicine if you are taking certain medicines (see "Do not take").

This medicine may also affect the way other medicines work. You should talk to your pharmacist if you are taking ANY other medicines, particularly if you are taking any of the following medicines:

- Medicines to thin your blood (e.g. warfarin)
- Rifabutin or rifampicin (for bacterial infections) or other anti-fungal medicines (including ketoconazole)
- Medicines to reduce cholesterol (e.g. statins)
- Medicines for high blood pressure, water tablets (diuretics), or for heart problems
- Amiodarone (used for rhythm disorders)
- Medicines for mental health conditions (e.g. triazolam, midazolam, or tricyclic antidepressants), or for epilepsy (e.g. carbamazepine or phenytoin)
- Methadone (for pain relief or treatment of opioid dependence)
- Fentanyl, alfentanil, or non steroidal anti-inflammatory medicines (for pain relief or inflammation)
- Medicines for diabetes
- Ibrutinib (used for treating blood cancer)
- Zidovudine or saquinavir (for HIV infection)
- Ciclosporin, sirolimus, or tacrolimus (given after transplant surgery, or for psoriasis or rheumatism)
- olaparib (used for treating ovarian cancer)
- ivacaftor (used for treating cystic fibrosis)
- verapamil (used to manage hypertension and angina)
- tolvaptan used to treat hyponatremia (low levels of sodium in your blood) or to slow kidney function decline

Any other medicines includes medicines prescribed by your doctor and medicine you have bought for yourself, including herbal and homeopathic remedies.

✓ **How to take this medicine**

Check the foil is not broken before use. If it is, do not take the capsule.

Age	How many to take	How often to take
Adults aged 16 to 60 years	One	Once only

Swallow the capsule whole with water.

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

Do not take more than the amount recommended above.

If symptoms do not go away within 7 days talk to your doctor.

If your symptoms worsen at any time talk to your doctor.

If symptoms clear up but then return after 7 days, you can take another capsule, unless you had an allergic reaction the first time.

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

! If you accidentally take a large number of capsules: Talk to a doctor or go to your nearest hospital casualty department straight away. 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 effects, stop using the medicine. See a doctor at once:

- Difficulty breathing, swelling of the face, neck, tongue or throat, low blood pressure, fainting (severe allergic reactions)
- Severe skin rash which may include peeling, blistering and lesions of the skin
- Liver problems such as yellowing of the skin or eyes, dark coloured urine, pale stools, or changes in the way your liver works (that may show up in blood tests)

You must not take fluconazole again if you experience any of these serious side effects.

This medicine may also cause these serious side effects. See a doctor at once if you notice:

- Changes in the heart rhythm (you may notice an irregular heart rate or beat)
- Changes in the blood which may cause severe tiredness or exhaustion, unusual bruising or an increase in the number of infections that you get (e.g. sore throats, mouth ulcers, flu-like symptoms including fever)
- Fits, or convulsions

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

- Feeling sick or being sick, heartburn, abdominal pain, diarrhoea, constipation, wind, dry mouth, taste disturbances, loss of appetite
- Difficulty sleeping or difficulty getting to sleep
- Headache, feeling dizzy or unsteady on your feet, pins and needles, pain in the muscles, weakness or loss of strength, general feeling of tiredness or being unwell, shaking
- Red, raised itchy skin rash, or a rash with eruptions of pus
- Increased sweating, rarely hair loss
- Low levels of potassium, rarely increased cholesterol or blood fat levels

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 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.

How to store this medicine

Do not store above 25°C.

Store in the original package.

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

The capsule contains Fluconazole 150 mg which is the active ingredient.

As well as the active ingredient the capsule also contains anhydrous lactose, maize starch, colloidal anhydrous silica, sodium laurilsulfate, magnesium stearate.

The capsule shell contains gelatin, titanium dioxide (E171), patent blue (E131), methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216).

The pack contains one hard blue gelatin capsule filled with white to off white powder.

Who makes this medicine

Manufactured for The Boots Company PLC Nottingham NG2 3AA by the Marketing Authorisation holder Bristol Laboratories Limited Unit 3 Canalside Northbridge Road Berkhamsted Herts HP4 1EG

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