
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
- 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.
- You must talk to your doctor if you do not feel better or if you feel worse after seven day.

What is in this leaflet?

1. What is Thrush 150mg Capsule and what is it used for
2. What you need to know before you take Thrush 150mg Capsule
3. How to take thrush 150mg Capsule
4. Possible side effects
5. How to store Thrush 150mg Capsule
6. Contents of the pack and other information

1. What this medicine is and what is it used 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

2. What you need to know 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 fluconazole, or any other anti-fungal medicine or you any of the other ingredients of this medicine (listed in section 6). The symptoms may include 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)
- **If you are suffering** from Tinea Capitis (fungal infection of the scalp)

Warnings and precautions

Talk to your doctor or pharmacist before taking this medicine

- 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
- If you develop severe skin reactions (itching, reddening of the skin or difficulty breathing)
- If you develop signs of ‘adrenal insufficiency’ where the adrenal glands do not produce adequate amounts of certain steroid hormones such as cortisol (chronic, or long lasting fatigue, muscle weakness, loss of appetite, weight loss, abdominal pain)
- If you have ever developed a severe skin rash or skin peeling, blistering and /or mouth sores after taking this medicine

Serious skin reactions including drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported in association with fluconazole treatment. Stop taking this medicine and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

Talk to your doctor or pharmacist if the fungal infection does not improve, as alternative antifungal therapy may be needed.

Other medicines and Thrush 150mg Capsules

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Tell your doctor **immediately** if you are taking astemizole, terfenadine (an antihistamine for treating allergies) or cisapride (used for stomach upsets) or pimozide (used for treating mental illness) or quinidine (used for treating mental illness) or erythromycin (an antibiotic for treating infections) as these should not be taken with this medicine (see section 2: “Do not take this medicine”).

There are some medicines that may interact with fluconazole. Make sure your doctor knows if you are taking any of the following medicines as a dose adjustment or monitoring may be required to check that the medicines are still having the desired effect.

- Rifabutin or rifampicin (antibiotics for infections)
- Alfentanil, Nortriptyline (used as anti-depressant)
- Amphotericin B, voriconazole (anti-fungal)
- Medicines that thin the blood to prevent blood clots (warfarin or similar medicines)
- Benzodiazepines (midazolam, triazolam or similar medicines) used to help you sleep or for anxiety
- Carbamazepine, phenytoin (used for treating fits)
- Nifedipine, isradipine, amlodipine, verapamil, felodipine and losartan (for hypertension – high blood pressure)
- Olaparib (used for treating ovarian cancer)
- Ciclosporin, everolimus, sirolimus or tacrolimus (to prevent transplant rejection)
- Cyclophosphamide, vinca alkaloids (vincristine, vinblastine or similar medicines) used for treating cancer
- Halofantrine (used for treating malaria)
- Statins (atorvastatin, simvastatin and Fluvastatin or similar medicines) used for reducing high cholesterol levels
- Methadone (used for pain)
- Celecoxib, fluriprofen, naproxen, ibuprofen, lornoxicam, meloxicam, diclofenac (Non-Steroidal Anti-Inflammatory Drugs (NSAID))
- Oral contraceptives
- Prednisone (steroid)
- Zidovudine, also known as AZT; saquinavir (used in HIV-infected patients)
- Medicines for diabetes such as chlorpropamide, glibenclamide, glipizide or tolbutamide
- Theophylline (used to control asthma)
- Tofacitinib (used for treating rheumatoid arthritis)
- Tolvaptan used to treat hyponatremia (low levels of sodium in your blood) or to slow kidney function decline
- Vitamin A (nutritional supplement)
- Ivacaftor (alone or combined with other drugs used for treating cystic fibrosis)
- Amiodarone (used for treating an uneven heartbeats ‘arrhythmias’)
- Hydrochlorothiazide (a diuretic)
- Ibrutinib (used for treating blood cancer)
- Lurasidone (used to treat schizophrenia)

Thrush Capsules with food and drink

You can take your medicine with or without a meal.

Pregnancy, breastfeeding and fertility

Pregnancy:

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. You should not take this medicine if you are pregnant, think you may be pregnant or are trying to become pregnant, unless your doctor has told you so. If you become pregnant while taking this medicine or within 1 week of the most recent dose, contact your doctor.

Fluconazole taken during the first trimester of pregnancy may increase the risk of miscarriage. Fluconazole taken at low doses during the first trimester may slightly increase the risk if a baby being born with birth defects affecting the bones and/or muscles.

Breast-Feeding

You can continue breast-feeding after taking a single dose of this medicine.

You should not breast-feed if you are taking a repeated dose of this medicine.

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:

- This medicine contains Lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
- 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'.

✓ How to take this medicine

Always take this medicine exactly as your doctor has told you. You should check you're your doctor or pharmacist if you are not sure. 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.

Not recommended in children under 16 years

Not recommended in patients aged over 60 years.

If you take more Thrush capsule than you should

Taking too many capsules at once may make you unwell. Contact your doctor or your nearest hospital casualty department at once. The symptoms of a possible overdose may include hearing, seeing, feeling and thinking things that are not real (hallucination and paranoid behaviour). Symptomatic treatment (with supportive measures and gastric lavage if necessary) may be adequate.

If you forget to take this medicine

Do not take a double dose to make up for a forgotten dose. If you forget to take a dose, take it as soon as you remember. If it is almost time for your next dose, do not take the dose that you missed.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Stop taking this medicine and seek medical attention **immediately** if you notice any of the following symptoms:

- wide spread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome)

A few people develop **allergic reactions** although serious allergic reactions are rare. If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. If you get any of the following symptoms, **tell your doctor immediately**.

- Sudden wheezing, difficulty in breathing or tightness of the chest
- Swelling of the eyelids, face or lips
- Itching all over the body, reddening of the skin or itchy red spots
- Skin rash
- Severe skin reactions such as a rash that causes blistering (this can affect the mouth and tongue).
This medicine may affect your liver. The signs of liver problems include:
 - Tiredness
 - Loss of appetite
 - Vomiting
 - Yellowing of your skin or the whiteness of your eyes (jaundice)

If any of these happen, stop taking this medicine and **tell your doctor immediately**.

Other side effects:

Additionally, if any of the following side effects gets serious, or you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Common side effects (may affect up to 1 in 10 people): Headache

- Stomach discomfort, diarrhoea, feeling sick, vomiting
- Increases in blood tests of liver function

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- Rash

Uncommon side effects (may affect up to 1 in 100 people)

- Reduction in red blood cells which can make skin pale and cause weakness or breathlessness
- Decreased appetite
- Inability to sleep, feeling drowsy
- fit, dizziness, sensation of spinning, tingling, prickling or numbness, changes in sense of taste
- Constipation, difficult digestion, wind, dry mouth
- Muscle pain
- Liver damage and yellowing of the skin and eyes (jaundice)
- Wheals, blistering (hives), itching, increased sweating
- Tiredness, general feeling of being unwell, fever

Rare side effects (may affect up to 1 in 1000 people):

- Lower than normal white blood cells that help to stop bleeding
- Red or purple discolouration of the skin which may be caused by low platelet count, other blood cell changes
- Blood chemistry changes (high blood levels of cholesterol, fats)
- Low blood potassium
- Shaking
- Abnormal electrocardiogram (ECG), change in heart rate or rhythm
- Liver failure
- Allergic reactions (sometimes severe) including widespread blistering rash and skin peeling, severe skin reactions, swelling of the lips or face
- Hair loss

Frequency not known, but may occur (cannot be estimated from the available data)

- Hypersensitivity reaction with skin rash, fever swollen glands, increase in a type of white blood cell (eosinophilia) and inflammation of internal organs (liver, lungs, heart, kidneys and large intestine) (Drug Reaction or rash with Eosinophilia and Systemic Symptoms (DRESS))

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 silicon dioxide, sodium lauryl sulfate, magnesium stearate.

The capsule shell contains Gelatin, Titanium Dioxide (E171), Patent blue V (E131), Methyl Parahydroxybenzoate (E218), Propyl Parahydroxybenzoate (E216) and sodium Lauryl Sulfate.

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 United Kingdom

Batch release site Wave Pharma Limited 4th Floor Cavendish House 369 Burnt Oak Broadway Edgware HA8 5AW United Kingdom

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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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