Read all of this leaflet carefully before you start taking this medicine. This medicine is available without prescription.

1. What Fluconazole 150mg Capsule is and what it is used for

Fluconazole 150mg Capsule is a full course of treatment for thrush. Only use this product if you have been previously diagnosed by your doctor as having thrush.

The active substance is Fluconazole. It belongs to a group of medicines called azoles and is an antifungal agent. It fights the cause of infections such as thrush.

2. Before you take Fluconazole 150mg Capsule

Do not take Fluconazole 150mg Capsule if you:

- are allergic (hypersensitive) to Fluconazole, or another drug from the same group of antifungal drugs (i.e. miconazole), or any of the other ingredients of Fluconazole 150mg Capsule (See section 6. Contents of the pack and other information)
- are taking another drug called terbinafine or itraconazole (antifungal), ciclosporin (a drug used in organ transplants), trichomoniasis (a sexually transmitted disease), or quinine (for heart diseases) or erythromycin (an antibiotic for treating infections)
- suffer from porphyria

Warnings and precautions

Before taking Fluconazole 150mg Capsule, you should see your doctor:

• if you are unsure about the cause of your symptoms
• if you are taking any other medicine or herbal product
• if you are pregnant or breastfeeding unless your doctor has told you to.

3. How to take Fluconazole 150mg Capsule

Fluconazole 150mg Capsule contains sunset yellow (E110) which may affect people with a hereditary deficiency of the enzyme alaphatase. People with this deficiency may have an allergic reaction to this colouring.

Fluconazole 150mg Capsule contains lactose monohydrate, a type of sugar which may cause an allergic reaction in people with lactose intolerance (a genetic deficiency of the enzyme lactase). If you have such an intolerance, make sure you read all summary information on the packaging before you buy this product.

Fluconazole 150mg Capsule contains sodium laurylsulfate, a type of surfactant that may cause an allergic reaction in people with this deficiency. If you have such an intolerance, make sure you read all summary information on the packaging before you buy this product.

4. Possible side effects

Like all medicines, Fluconazole Capsules can cause side effects, although not everyone gets them.

STOP taking Fluconazole 150mg Capsule straight away and contact your doctor immediately if you experience:

• a serious allergic reaction (anaphylaxis) or any sensitivity including an itching rash (hives), itching, some mouth or eyes, swelling of the face, lips, throat or tongue
• a sudden wheeziness or tightness of the chest
• liver problems or yellowing of the skin or whites of the eyes (jaundice), dark coloured urine, or changes in the way your liver works (that may show up in blood tests)
• a severe rash with flushing, fever, blisters or ulcers (Stevens-Johnson syndrome)
• a severe rash with peeling and swelling of the skin that looks like a burn (toxic epidermal necrolysis)

The following side-effects are usually mild. However, if you suffer from any of these they are severe or prolonged, please inform your doctor or pharmacist.

Common: may affect up to 1 in 10 people

• headache
• stomach discomfort, diarrhea, feeling sick, vomiting
• increases in blood levels of liver function

Uncommon: may affect up to 1 in 100 people

• anemia, reduction in red blood cells which can make skin pale and feel cold
• constipation
• decreased appetite
• inability to sleep, feeling drowsy
• fits, dizziness, sensation of spinning, tingling, pricking or numbness, changes in sense of taste
• indigestion, flatulent, dry mouth
• muscle pain
• low blood pressure, which may cause muscle cramps or weakness, nausea and changes in heart rhythm
• increased sweating
• tiredness, general feeling of being unwell, fever

Rar: may affect up to 1 in 1,000 people

• lower than normal white blood cells (which you may have more infections than usual) or sore throat, fever or flu-like symptoms
• lower than normal blood cell levels that help to stop bleeding (you may have easier bruising or bleeding)
• red or purple discoloration of the skin which may be caused by low platelet count
• blood chemistry changes (high blood levels of cholesterol, fats)
• shaking
• abnormal electrocardiogram (ECG), change in heart rate or rhythm

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.

5. How to store Fluconazole 150mg Capsule

Keep out of the sight and reach of children

Fluconazole 150mg Capsule is a yellow capsule. Each pack contains a blister pack of 1 capsule.

Marketing Authorisation Holder
Aphlone Pharmaceuticals Limited, Ballymurry, Co. Roscommon, Ireland.

Company responsible for release of this product to market
Kent Pharmaceuticals Limited, Cranbrooke Road, Ashford, Kent, TN32 4GR, U.K.

Kent Pharmaceuticals Limited, Repton Road, Measham, DE12 7TD, U.K.

Distributor
Kent Pharmaceuticals Limited, Repton Road, Measham, DE12 7TD, U.K.

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Further information about thrush

Vaginal thrush (candidiasis) is a common infection that most women suffer from at some stage in their lives and is not caused by lack of personal hygiene.

Thrush is caused by a yeast (fungus) called Candida, which lives harmlessly in the vagina and other parts of the body without ever being noticed.

However, the natural balance that keeps Candida under control can be upset by many factors such as hormonal changes (menstruation, contraceptive pill, pregnancy, menopause), poor health, antibiotics, perfumed soaps, bath additives and tight clothing.

If the pH balance is altered, the level of yeast increases and can develop into a thrush infection causing any of the following symptoms: persistent burning and/or itching around the vagina and vulva, redness, swelling and soreness of the tissues of the vagina and vulva and a white, odourless discharge from the vagina.

Not everybody who has thrush has all these symptoms, you may have only one or two of the symptoms.

In men, Candida can also cause thrush – a condition called balanitis (inflammation of the end of the penis). It causes any of the following symptoms: soreness and redness of the penis, tightness of the foreskin and a white, odourless discharge from the penis.

How to avoid recurrences

• Wear cotton underwear and avoid tight clothing
• Wash daily
• After going to the toilet, wipe yourself from front to back as a thrush infection may be transferred from the bowels
• Change your sanitary protection regularly
• Wear cotton underwear and avoid tight clothing
• Try to avoid wearing with perfumed soaps and using vaginal deodorants
• Do not wash or rub your hand with sponges or flannels

If you are still worried or have any questions about the symptoms or the treatment of thrush, contact your doctor or pharmacist for advice.

The leaflet was last revised May 2018.