

FLUCONAZOLE 150 mg CAPSULE



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

- 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 pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 7 days.

- What is in this leaflet:**
1. What Fluconazole 150 mg Capsule is and what it is used for
 2. What you need to know before you take Fluconazole 150 mg Capsule
 3. How to take Fluconazole 150 mg Capsule
 4. Possible side effects
 5. How to store Fluconazole 150 mg Capsule
 6. Contents of the pack and other information

1. WHAT FLUCONAZOLE 150 mg CAPSULE IS AND WHAT IT IS USED FOR

Fluconazole 150 mg 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. WHAT YOU NEED TO KNOW BEFORE YOU TAKE FLUCONAZOLE 150 mg CAPSULE

Do not take Fluconazole 150 mg Capsule if you:

- are allergic (hypersensitive) to fluconazole, or another drug from the same group of antifungal drugs (i.e. imidazoles), or any of the other ingredients of Fluconazole 150 mg Capsule (See section 6, Contents of the pack and other information)
- are taking another drug called terfenadine or astemizole (antihistamines), cisapride (a drug used to treat acid reflux, indigestion or decreased gastric motility), pimozide (a psychiatric medicine), quinidine (for heart disease) or erythromycin (an antibiotic for treating infections)
- suffer from porphyria

Warnings and precautions

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

- are unsure about the cause of your symptoms
- have had thrush more than twice in the last six months
- or your partner have ever been exposed to a sexually transmitted disease
- are taking any medicine other than the contraceptive pill
- are aged under 16 or over 60 years
- have had any disease or illness affecting the liver or kidneys, or have had any unexplained jaundice (yellowing of the skin and eyes)
- suffer from heart disease, including heart rhythm problems
- suffer from any other chronic disease or illness
- 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)
- have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking fluconazole
- if the fungal infection does not improve, as alternative antifungal therapy may be needed.

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

Women only:

- If you are pregnant, suspect you might be pregnant or are breast-feeding.
- If you have any abnormal or irregular vaginal bleeding or a blood stained discharge.
- If you have vulval or vaginal sores, ulcers or blisters.
- If you are experiencing lower abdominal pain or burning on passing urine.

Men only:

- If your sexual partner does not have vaginal thrush.
- If you have penile sores, ulcers or blisters.
- If you have an abnormal penile discharge (leakage).
- If your penis has started to smell.
- If you have pain on passing urine.

Children (under 16 years):

Paediatric use is not recommended.

Other Medicines and Fluconazole 150 mg Capsule

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Inform your doctor if you are taking:

- Amiodarone (used for treating uneven heartbeats 'arrhythmias')
- Cisapride (for stomach upsets)
- Terfenadine or astemizole (antihistamines)
- Pimozide (a psychiatric medicine)

- Quinidine or calcium channel blockers (for heart disease)
- Rifampicin, rifabutin or erythromycin (antibiotics)
- Diuretics e.g. hydrochlorothiazide (used to treat fluid retention and high blood pressure)
- Losartan (used to treat high blood pressure)
- Warfarin or coumarin-type anticoagulant medicines (used to prevent blood clots)
- Benzodiazepines e.g. midazolam, triazolam (used as tranquilisers)
- Oral sulphonylureas e.g. chlorpropamide, glibenclamide, glipizide or tolbutamide (used to control diabetes)
- Phenytoin or carbamazepine (used to control epilepsy)
- Ciclosporin, everolimus, sirolimus or tacrolimus (used to affect the immune response)
- Theophylline (used to control asthma)
- Zidovudine, also known as AZT, or saquinavir (used in HIV-infected patients)
- Prednisone (used to treat allergies)
- Oral contraceptives
- Opioids such as alfentanil, fentanyl and methadone (used for pain relief or anaesthesia)
- Non-steroidal anti-inflammatory medicines such as aspirin, celecoxib
- The anti-depressants amitriptyline and nortriptyline
- Amphotericin B, voriconazole (used to treat fungal infections)
- Cyclophosphamide and vinca alkaloids (used in chemotherapy)
- Halofantrine (used to treat malaria)
- HMG-CoA reductase inhibitors (statins (atorvastatin, simvastatin and fluvastatin or similar medicines) used for reducing high cholesterol levels)
- Vitamin A
- Ivacaftor (used for treating cystic fibrosis)
- Tofacitinib (used for treating rheumatoid arthritis)
- Olaparib (used for treating ovarian cancer)
- Abrocitinib (used for treating atopic dermatitis)
- Ibrutinib (used for treating cancer)
- Lurasidone (used for treating schizophrenia and bipolar disorder)
- Tolvaptan (used for hyponatremia)

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

If you are planning to become pregnant, it is recommended to wait a week after a single dose of fluconazole before becoming pregnant.

For longer courses of treatment with fluconazole, talk to your doctor on the need for appropriate contraception during treatment which should continue for one week after the last dose.

You should not take fluconazole if you are pregnant, think you may be pregnant, are trying to become pregnant or breast-feeding, 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 or second trimester of pregnancy may increase the risk of miscarriage. Fluconazole taken during the first trimester may increase the risk of a baby being born with birth defects affecting the heart, bones and/or muscles.

There have been reports of babies born with birth defects affecting the skull, ears, and bones of the thigh and elbow in women treated for three months or more with high doses (400-800 mg daily) of fluconazole for coccidioidomycosis. The link between fluconazole and these cases is not clear.

Driving and using machines

Fluconazole Capsules are unlikely to affect your ability to drive or use machinery, however, when driving or operating machines it should be taken into account that occasionally dizziness or seizures may occur.

Important information about some of the ingredients of Fluconazole 150 mg Capsule

Fluconazole 150 mg Capsule contains lactose monohydrate, a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. Fluconazole 150 mg Capsule contains sunset yellow (E110) which may cause allergic reactions.

Customer: IS

Originated by: ABC (AWG)

Product: Fluconazole 150 mg Capsule POM

Dimensions: 160mm x 400mm

Item Code: CP.FLC.150C.P.IS.V15P1

Proof and Date: 1 22/01/2024

Revision: Brand Review

ARTWORK FOR SUBMISSION
Supersedes: V14P1

Colours



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

3. HOW TO TAKE FLUCONAZOLE 150 mg CAPSULE

Always take this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

Fluconazole is taken orally.

Adults: 16 - 60 years

The full course of treatment consists of a single Fluconazole 150 mg Capsule. The capsule is to treat thrush at the site of infection and should be swallowed whole with a glass of water.

The symptoms of thrush should disappear within two days of treatment. If no improvement is seen after seven days, you must tell your doctor. If the infection returns after seven days another capsule may be taken but if you have more than two infections within 6 months you should see your doctor.

If you take more Fluconazole 150 mg Capsule than you should

If you or someone else swallows more than one capsule at once, contact your doctor, pharmacist or hospital emergency department immediately. Always take any capsules left over with you and also the box, as this will allow easier identification of the capsules.

4. POSSIBLE SIDE EFFECTS

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

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

- a serious allergic reaction (anaphylaxis) or hypersensitivity including an itchy rash (hives), itching, sore mouth or eyes, fever, swelling of the face, lips, throat or tongue
- a sudden wheeziness or tightness of the chest
- liver problems such as 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 skin rash with flushing, fever, blisters or ulcers (Stevens-Johnson syndrome)
- a severe rash with reddening, peeling and swelling of the skin that looks like a burn (toxic epidermal necrolysis)
- 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)
- Widespread rash, high body temperature and enlarged lymph node (DRESS syndrome or drug hypersensitivity syndrome).

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

Common: may affect up to 1 in 10 people

- headache
- stomach discomfort, diarrhoea, feeling sick, vomiting
- increases in blood tests of liver function
- rash

Uncommon: may affect up to 1 in 100 people

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

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

- lower than normal white blood cells (you may have more infections than usual such as sore throats, fever or flu-like symptoms)
- lower than normal blood cells that help to stop bleeding (you may have unexplained 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
- hair loss

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 150 mg CAPSULE

KEEP OUT OF THE SIGHT AND REACH OF CHILDREN

Do not use Fluconazole 150 mg Capsule after the expiry date, which is stated on the carton. The expiry date refers to the last day of that month. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Fluconazole 150 mg Capsule contains

The active substance is fluconazole. Each capsule contains 150 mg fluconazole. The other ingredients are lactose monohydrate, microcrystalline cellulose, maize starch, sodium laurilsulfate, colloidal anhydrous silica and magnesium stearate.
The capsule shell contains:
Titanium dioxide (E171), Quinoline yellow (E104), sunset yellow (E110) and gelatin.

What Fluconazole 150 mg Capsule looks like and contents of the pack

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

Marketing Authorisation Holder

Kent Pharma UK Limited, 2nd Floor, Connect 38, 1 Dover Place, Ashford, Kent, England, TN23 1FB.

Company responsible for release of this product to market

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

PL 51463/0080

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 natural 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 the vulva and a whitish, odourless discharge from the vagina.

Not everybody who has thrush has all these symptoms; you may have only one of them.

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 future 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 bowel
- Change your sanitary protection regularly
- Try to avoid washing with perfumed soaps and using vaginal deodorants
- Do not wash or rub yourself hard 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 February 2024.