

PATIENT INFORMATION LEAFLET

FLUCONAZOLE 150mg CAPSULE

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

- **Keep this leaflet. You may need to read it again**
- **Ask your pharmacist if you need more information or advice**
- **You should contact your doctor if your symptoms worsen or do not improve in 7 days**
- **If you have any unusual effects after taking this product, tell your doctor or pharmacist.**

IN THIS LEAFLET

1. What Fluconazole 150mg Capsule is and what it is used for
2. Before you take Fluconazole 150mg Capsule
3. How to take Fluconazole 150mg Capsule
4. Possible side effects
5. How to store Fluconazole 150mg Capsule
6. Further Information

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 or any of the other ingredients of Fluconazole 150mg Capsule (See section 6, further information)
- Are taking another drug called terfenadine (an antihistamine), or cisapride (for stomach problems)

Take special care with Fluconazole 150mg Capsule

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

- You are unsure whether you have thrush or this is the first time you have had these symptoms
- You have had more than two infections of thrush in the last 6 months
- You or your partner have ever been exposed to a sexually transmitted disease
- You are taking any medicine other than the pill
- You are aged under 16 or over 60
- You have ever had an allergic reaction to fluconazole or any other vaginal antifungal products
- You have had any disease or illness affecting the liver or kidneys, or have had any unexplained jaundice (yellowing of the skin and eyes)
- You suffer from any other chronic disease or illness
- You are a woman **and you have**
 - o Abnormal or irregular vaginal bleeding or a blood-stained discharge
 - o A foul smelling discharge from the vagina

- Lower stomach pain, fever or chills, or pain or burning sensation on passing urine
- Ulcers, blisters or sores of the vagina or vulva
- Diarrhoea or are feeling sick or vomiting
- You are a man **and**
 - Your sexual partner **does not** have thrush
 - You have sores, ulcers or blisters on your penis
 - You have an abnormal discharge from your penis
 - Your penis has started to smell
 - You have pain or difficulty in passing urine.

Taking other medicines

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

Do not use fluconazole 150mg Capsule if you are taking the antihistamine terfenadine or the medicine cisapride.

Inform your doctor if you are taking:

- Anticoagulants, to prevent blood clots
- Sulphonylureas, to control diabetes
- Hydrochlorothiazide, used to treat fluid retention and high blood pressure
- Benzodiazepines, used as tranquillisers
- Phenytoin, used to treat epilepsy
- Rifampicin or Rifabutin, types of antibiotics
- Ciclosporin or Tacrolimus, used to reduce the immune response
- Theophylline, used to control asthma
- Zidovudine, used to treat HIV infection
- Astemizole, a type of antihistamine
- The contraceptive “pill”
- Cimetidine or other antacids, used to treat heartburn or stomach ulcers.

Pregnancy and breast-feeding

Do not use Fluconazole 150mg Capsule if you are pregnant, trying to get pregnant or are breast-feeding

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 150mg Capsule

Fluconazole 150mg 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 150mg Capsule contains sunset yellow E110 which may cause allergic reactions.

3. HOW TO TAKE FLUCONAZOLE 150mg CAPSULE

If this product was prescribed for you by a doctor, you should take Fluconazole 150mg Capsule exactly as he/she has told you. If you purchased this product without a prescription, follow these directions closely:

The full course of treatment consists of a single Fluconazole 150mg 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 150mg 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 150mg Capsule can cause side effects, although not everybody gets them. As with all medicines, some people may be allergic to the capsule. If you are allergic, a reaction will occur soon after you have taken it. If you experience an allergic reaction, stop using this product and tell your doctor straight away or contact your nearest hospital emergency department. Signs of an allergic reaction may include:

- Rash
- Swallowing or breathing problems
- Swelling of your lips, face, throat or tongue
- Weakness, feeling dizzy or faint
- Nausea

The most common side effects are:

- Sickness or stomach discomfort
- Diarrhoea and wind

Rarely, people have experienced:

- Headaches
- Liver disorders

The following have been reported rarely by some patients, but it may not be due to this medicine:

- Skin disorders and unexpected bruising
- Seizures
- Hair loss
- Recurrent infections (e.g. cold and flu)

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

5 HOW TO STORE FLUCONAZOLE 150mg CAPSULE

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN

Do not use Fluconazole 150mg 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. FURTHER INFORMATION

What Fluconazole 150mg Capsule contains

The active substance is fluconazole. Each capsule contains 150mg 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), Quinilone yellow (E104), sunset yellow (E110) and gelatin.

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

Fluconazole 150mg capsule is a yellow capsule.

Each pack contains a blister pack of 1 capsule.

Marketing Authorisation Holder

Athlone Pharmaceuticals Limited, Ballymurray, Co. Roscommon, Ireland

Company responsible for release of this product to market

Kent Pharmaceuticals Ltd. Crowbridge Road, Ashford, Kent TN24 0GR, U.K

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

Distributor

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PL 30464/0147

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 March 2013.