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 doctor 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.

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. imidazoles), or any of the other ingredients of Fluconazole 150mg Capsule (see section 6. Contents of the pack and other information).
- are taking another medicine such as isefaldone or azolestan (imidazoles), cisapride (used to treat acid reflux, indigestion or decreased gastric mobility), molindone (a psychiatric medicine) or quinidine (for heart disease).

3. HOW TO TAKE FLUCONAZOLE 150mg CAPSULE

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

- you have had any unexplained jaundice (yellowing of the skin and eyes). Yellowing of the skin and eyes (jaundice) can be a sign of serious liver problems such as hepatitis or gallstones, but uncommonly it may occur in patients being treated with fluconazole.
- you have had thrush more than twice in the last six months.
- you or your partner has had a sexually transmitted disease.
- you are pregnant or planning to become pregnant.
- you are a frequent smoker or an ex-smoker.
- you have any other serious medical condition.

4. POSSIBLE SIDE EFFECTS

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

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

- a serious allergic reaction (anaphylaxis) or hypersensitivity including an itching rash, itching, some mouth or eyes, fever, swelling of the face, lips, throat or tongue
- a painful and persistent headache
- 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 peeling, swelling and peeling of the skin that looks like a burn (Toxic epidermal necrolysis)

The following side effects are usually mild. However, if you suffer these side effects 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
- changes in sense of taste
- indigestion, wind, flatulence, chest 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

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 unusual 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)
- abnormal electrocardiogram (ECG), change in heart rate or rhythm
- hair loss

Important information about some of the ingredients of Fluconazole 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 the product without a prescription, follow these directions closely.

Adults - 18 to 65 years

Full course of treatment consists of a single Fluconazole 150mg Capsule. The capsule is to be taken thrice 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 are taking more than one capsule at time, 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.

The capsule shell contains:

- Titanium dioxide (E171), Quinoline 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

Asthana Pharmaceuticals Limited, Ballymoy, Co. Roscommon, Ireland.

Company responsible for release of this product to market

Kent Pharmaceuticals Limited, Crossbridge Road, Anerley, Kent, TN24 9GR, U.K.

Distributor

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

PL 20046/147

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, performed 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 to yellowish 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 you of 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,a clean and dry clothing
- Wash daily
- After going to the toilet, wipe yourself from front to back as a thrush infection may be transmitted from the bowel to the genital area
- Change your sanitary protection
- Try to avoid washing with perfumed soaps and using vaginal deodorants
- Do not wash or rub yourself hard with sponges or towels

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 January 2017.

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Product: Fluconazole 150mg Capsule P
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