

Public Assessment Report

Fluconazole 150mg Capsule

PL 00289/0708

FLUCONAZOLE 150MG CAPSULE

PL 00289/0708

UKPAR

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FLUCONAZOLE 150MG CAPSULE

PL 00289/0708

LAY SUMMARY

The Medicines and Healthcare products Regulatory Agency (MHRA) has granted Teva UK Limited a Marketing Authorisation (licence) for the medicinal product Fluconazole 150mg Capsule (PL 00289/0708). This is a pharmacy [P] medicine for treating vaginal thrush, a fungal infection.

Fluconazole is an antifungal that works by interfering with the normal functioning of a yeast called *Candida albicans*.

This is a simple abridged application that cross-refers to a previously granted licence for Fluconazole 150mg Capsule (PL 00289/0485).

No new or unexpected safety concerns arose from this simple application and it was therefore judged that the benefits of using Fluconazole 150mg Capsule outweigh the risks, hence a Marketing Authorisation has been granted.

FLUCONAZOLE 150MG CAPSULE

PL 00289/0708

SCIENTIFIC DISCUSSION

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INTRODUCTION

The UK granted a marketing authorisation for the medicinal product Fluconazole 150mg Capsule (PL 00289/0708) to Teva UK Limited on 3 April 2006. The product is a pharmacy [P] medicine.

This application was submitted as a simple abridged application according to Article 10.1(a)i of Directive 2001/83/EC, cross-referring to Fluconazole 150mg Capsule (PL 00289/0485, approved on 18 October 2002).

Fluconazole, a member of the triazole class of antifungal agents, is a potent and selective inhibitor of fungal enzymes necessary for the synthesis of ergosterol.

No new data were submitted for this simple application, nor were any necessary, as the data are identical to that of the previously granted cross-referenced product. As the cross-referenced product was granted prior to the introduction of current legislation, no public assessment report was generated for it.

Fluconazole 150mg Capsule is used for the treatment of vaginal candidiasis, acute or recurrent. It may also be used for the treatment of partners with associated candidal balanitis.

PHARMACEUTICAL ASSESSMENT

LICENCE NO.: PL 00289/0708
PRODUCT NAME: Fluconazole 150mg Capsule
ACTIVE(S): Fluconazole
COMPANY NAME: Teva UK Ltd.
E.C. ARTICLE: 10.1(a)(i)
LEGAL STATUS: P

INTRODUCTION

This is a simple application “piggy-backed” to PL 00289/0485 held by Approved Prescription Services Limited (APS), Brampton, Eastbourne (Company no. 289). APS recently changed its name to Teva UK Ltd.

The applicant Teva UK Ltd, Brampton, Eastbourne (Company no. 289) is also the marketing authorisation holder of the cross-referenced product.

The proposed manufacturer is also the manufacturer of the cross-referenced product, therefore no letter of consent is included.

No issues or alerts were flagged for the cross-referenced product.

The experts (quality, non-clinical and clinical) have each declared to carry out their duties set out in Article 12.2 and in accordance with Annex I, Part I, 1.4 of Directive 2001/83/EC, as amended. A statement clearly indicating that the product and all of the product particulars are identical in all aspects to the referred product including the SPC has been provided.

Certificates of Suitability in compliance with the Ph.Eur. requirements for confirmation of TSE risk minimisation was provided for the gelatin component of the hard capsule.

PRODUCT NAME AND APPEARANCE

The generic name of the authorised product will still be used, bearing on the outside packaging box the applicant’s name as MAH, as well as its logo on the product’s blister foils.

SUMMARY OF PRODUCT CHARACTERISTICS (SPC)

SPC is identical to that of the cross-referenced product, with the effective changes, as per this application, regarding the MAH name and address details and marketing authorisation number.

PATIENT INFORMATION LEAFLET

The included part of the PIL is identical to that of the cross-referenced product with the exception of the name of the MAH and the effective changes as per this application.

LABELLING

Labelling is in line with the authorised product.

THE APPLICATION FORM

Satisfactory.

CONCLUSION

A Marketing Authorisation may be granted.

PRECLINICAL ASSESSMENT

No new preclinical data have been supplied with this application and none are required for an application of this type.

CLINICAL ASSESSMENT

No new clinical data have been supplied with this application and none are required for an application of this type.

OVERALL CONCLUSION AND RISK-BENEFIT ASSESSMENT

QUALITY

The data for this application are consistent with those previously assessed for the cross-referenced product and as such have been judged to be satisfactory.

PRECLINICAL

No new preclinical data were submitted and none are required for an application of this type.

EFFICACY

This application is identical to a previously granted application for Fluconazole 150mg Capsule.

No new or unexpected safety concerns arose from this application.

The SPC, PIL and labelling are satisfactory and consistent with those of the cross-referenced product.

RISK-BENEFIT ASSESSMENT

The quality of the product is acceptable and no new preclinical or clinical safety concerns have been identified. The applicant's product is identical to the cross-referenced product. Extensive clinical experience with the active ingredient fluconazole is considered to have demonstrated the therapeutic value of the compound. The risk-benefit assessment is therefore considered to be favourable.

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STEPS TAKEN FOR ASSESSMENT

1	The MHRA received the marketing authorisation application for Fluconazole 150mg Capsule on 27 May 2005.
2	Following standard checks the MHRA informed the applicant that its application was considered valid on 5 June 2005.
3	The MHRA's assessment of the submitted data was completed on 22 July 2005.
4	Further information was requested from the company on 22 July 2005.
5	The applicant submitted its response to further information request in a letter dated 7 September 2005.
6	Further information was requested from the company on 11 October 2005.
7	The applicant submitted its response to further information request in a letter dated 3 November 2005.
8	Additional information was requested from the company on 29 November 2005.
9	The applicant submitted its response to additional information request in a letter dated 13 December 2005.
10	The MHRA completed its assessment of the application on 31 January 2006.
11	The application was determined on 3 April 2006.

FLUCONAZOLE 150MG CAPSULE

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STEPS TAKEN AFTER AUTHORISATION - SUMMARY

Date submitted	Application type	Scope	Outcome

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Fluconazole 150 mg Capsule

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains 150 mg of fluconazole.
For excipients, see 6.1.

3. PHARMACEUTICAL FORM

Hard capsules
Gelatine capsules filled with white to yellowish white homogeneous powder, with a light blue opaque cap and light blue opaque body.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Fluconazole is indicated for the treatment of vaginal candidiasis, acute or recurrent. It may also be used for the treatment of partners with associated candidal balanitis.

4.2. Posology and method of administration

Adults (aged 16 to 60 years of age)

Candidal vaginitis or balanitis: 150 mg single oral dose.

Children (under 16 years of age)

Not recommended.

Elderly

Not recommended in patients over 60 years of age.

Renal Impairment

No adjustments in single dose therapy are necessary.

4.3. Contraindications

Fluconazole should not be used in patients with known hypersensitivity to fluconazole, related azole compounds or any other ingredient in the formulation.

Co-administration of terfenadine or cisapride is contra-indicated in patients receiving fluconazole. (See Interactions with other medicinal products and other forms of Interaction)

4.4. Special warnings and precautions for use

The product intended for pharmacy availability without prescription will carry a leaflet, which will advise the patient:

Do not use Fluconazole 150 mg Capsule without first consulting your doctor:

If you are under 16 or over 60 years of age.

If you are allergic to any of the ingredients in Fluconazole 150 mg Capsule or other antifungals and other thrush treatments (see section after taking Fluconazole 150 mg Capsule).

If you are taking any medicine other than the Pill.

If you are taking the antihistamine terfenadine or the prescription medicine cisapride.

If you have had thrush more than twice in the last six months.

If you have any disease or illness affecting your liver or kidneys or have had unexplained jaundice.

If you suffer from any other chronic disease or illness.

If you or your partner have had exposure to a sexually transmitted disease.

If you are unsure about the cause of your symptoms.

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 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 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.

This product should never be used again if the patient experiences a rash or anaphylaxis following the use of the drug.

Recurrent use (men and women):

Patients should be advised to consult their doctor if the symptoms have not been relieved within one week of taking Fluconazole 150 mg Capsule. Fluconazole 150 mg Capsule can be used again if the candidal infection returns after seven days. However, if the candidal infection recurs more than twice in six months, patients should be advised to consult their doctor.

Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

4.5. Interactions with other medicinal products and other forms of interaction

The following drug interactions relate to the use of multiple-dose fluconazole and the relevance to single-dose 150mg fluconazole has not yet been established.

Anticoagulants In an interaction study, fluconazole increased the prothrombin time (12%) after warfarin administration in healthy males. In post-marketing experience, as with other azole antifungals, bleeding events (bruising, epistaxis, gastrointestinal bleeding, haematuria and melaena) have been reported in association with increases in prothrombin time in patients receiving fluconazole concurrently with warfarin. Prothrombin time in patients receiving coumarin-type anticoagulants should be carefully monitored.

Rifampicin Concomitant administration of fluconazole and rifampicin resulted in a 25% decrease in the AUC and 20% shorter half-life of fluconazole. In patients receiving concomitant rifampicin, an increase in the fluconazole dose should be considered.

Hydrochlorothiazide In a kinetic interaction study, co-administration of multiple-dose hydrochlorothiazide to healthy volunteers receiving fluconazole increased plasma concentrations of fluconazole by 40%. An effect of this magnitude should not necessitate a change in the fluconazole dose regimen in subjects receiving concomitant diuretics, although the prescriber should bear it in mind.

Sulphonylureas Fluconazole has been shown to prolong the serum half-life of concomitantly administered oral sulphonylureas (chlorpropamide, glibenclamide, glipizide and tolbutamide) in healthy volunteers. Fluconazole and oral sulphonylureas may be co-administered to diabetic patients, but the possibility of a hypoglycaemic episode should be borne in mind.

Phenytoin Concomitant administration of fluconazole and phenytoin may increase the levels of phenytoin to a clinically significant degree. If it is necessary to administer both drugs concomitantly, phenytoin levels should be monitored and the phenytoin dose adjusted to maintain therapeutic levels.

Oral contraceptives Two kinetic studies with combined oral contraceptives have been performed using multiple doses of fluconazole. There were no relevant effects on either hormone level in the 50mg fluconazole study, while at 200mg daily the AUCs of ethinylestradiol and levonorgestrel were increased 40% and 24% respectively. Thus multiple dose use of fluconazole at these doses is unlikely to have an effect on the efficacy of the combined oral contraceptive.

Endogenous steroid Fluconazole 50mg daily does not affect endogenous steroid levels in females: 200-400mg daily has no clinically significant effect on endogenous steroid levels or on ACTH stimulated response in healthy male volunteers.

Cyclosporin A kinetic study in renal transplant patients found fluconazole 200mg daily to slowly increase cyclosporin concentrations. However, in another multiple dose study with 100mg daily, fluconazole did not affect cyclosporin levels in patients with bone marrow transplants. Cyclosporin plasma concentration monitoring in patients receiving fluconazole is recommended.

Theophylline In a placebo controlled interaction study; the administration of fluconazole 200mg for 14 days resulted in an 18% decrease in the mean plasma clearance of theophylline. Patients who are receiving high doses of theophylline or who are otherwise at increased risk for theophylline toxicity should be observed for signs of theophylline toxicity while receiving fluconazole and the therapy modified appropriately if signs of toxicity develop.

Terfenadine Because of the occurrence of serious dysrhythmias secondary to prolongation of the QTc interval in patients receiving other azole antifungals in conjunction with terfenadine, interaction studies have been performed. One study at a 200mg daily dose of fluconazole failed to demonstrate a prolongation in QTc interval. Another study at a 400mg and 800mg daily dose of fluconazole demonstrated that fluconazole taken in multiple doses of 400mg per day or greater significantly increased plasma levels of terfenadine when taken concomitantly. There have been spontaneously reported cases of palpitations, tachycardia, dizziness, and chest pain in patients taking concomitant fluconazole and terfenadine where the relationship of the reported adverse events to drug therapy or underlying medical conditions was not clear. Because of the potential seriousness of such an interaction, it is recommended that terfenadine not be taken in combination with fluconazole. (See 'Contra-indications'.)

Cisapride There have been reports of cardiac events including torsades de pointes in patients to whom fluconazole and cisapride were co-administered. In most of these cases, the patients appear to have been predisposed to arrhythmias or had serious underlying illnesses, and the relationship of the reported events to a possible fluconazole-cisapride drug interaction is unclear. Because of the potential seriousness of such an interaction, co-administration of cisapride is contra-indicated in patients receiving fluconazole. (See 'Contra-indications'.)

Zidovudine Two kinetic studies resulted in increased levels of zidovudine most likely caused by the decreased conversion of zidovudine to its major metabolite. One study determined zidovudine levels in AIDS or ARC patients before and following fluconazole 200mg daily for 15 days. There was a significant increase in zidovudine AUC (20%). A second randomised, two-period, two-treatment cross-over study examined zidovudine levels in HIV infected patients. On two occasions, 21 days apart, patients received zidovudine 200mg every eight hours either with or without fluconazole 400mg daily for seven days. The AUC of zidovudine significantly increased (74%) during co-administration with fluconazole. Patients receiving this combination should be monitored for the development of zidovudine-related adverse reactions.

Rifabutin There have been reports that an interaction exists when fluconazole is administered concomitantly with rifabutin, leading to increased serum levels of rifabutin. There have been reports of uveitis in patients to whom fluconazole and rifabutin were co-administered. Patients receiving rifabutin and fluconazole concomitantly should be carefully monitored.

Tacrolimus There have been reports that an interaction exists when fluconazole is administered concomitantly with tacrolimus, leading to increased serum levels of tacrolimus. There have been reports of nephrotoxicity in patients to whom fluconazole and tacrolimus were co-administered. Patients receiving tacrolimus and fluconazole concomitantly should be carefully monitored.

The use of fluconazole in patients concurrently taking astemizole or other drugs metabolised by the cytochrome P450 system may be associated with elevations in serum levels of these drugs. In the absence of definitive information, caution should be used when co-administering fluconazole. Patients should be carefully monitored.

Interaction studies have shown that when oral fluconazole is co-administered with food, cimetidine, antacids or following total body irradiation for bone marrow transplantation, no clinically significant impairment of fluconazole absorption occurs.

Physicians should be aware that drug-drug interaction studies with other medications have not been conducted, but that such interactions may occur.

4.6. Pregnancy and lactation

Use during pregnancy

There are no adequate and well-controlled studies in pregnant women. There have been reports of multiple congenital abnormalities in infants whose mothers were being treated for 3 or more months with high dose (400-800 mg/day) fluconazole therapy for coccidioidomycosis. The relationship between fluconazole and these events is unclear. Accordingly, fluconazole should not be used in pregnancy or in women of childbearing potential unless adequate contraception is employed.

Use during lactation

Fluconazole is found in human breast milk at concentrations similar to plasma, hence its use in nursing mothers is not recommended.

4.7. Effects on ability to drive and use machines

Experience with fluconazole indicates that therapy is unlikely to impair a patient's ability to drive or use machinery.

4.8. Undesirable effects

Fluconazole is generally well tolerated. The most common side effects associated with fluconazole are symptoms related to the gastro-intestinal tract including nausea, abdominal discomfort, diarrhoea and flatulence. Other adverse events such as rash are rarely encountered (less than 1%). Headache has been associated with fluconazole.

Rare cases of hepatotoxicity, usually reversible on discontinuation of therapy, have been reported.

Exfoliative skin disorders, seizures, leucopenia including neutropenia and agranulocytosis, thrombocytopenia and alopecia have occurred under conditions where casual association is uncertain.

In rare cases, as with other azoles, anaphylaxis has been reported.

4.9. Overdose

There have been reports of overdosage with fluconazole. A 42 year-old patient infected with human immunodeficiency virus developed hallucinations and exhibited paranoid behaviour after reportedly ingesting 8200 mg of fluconazole, unverified by his physician. The patient was admitted to the hospital and his condition resolved within 48 hours.

In the event of overdosage, supportive measures and symptomatic treatment, with gastric lavage, may be necessary.

As fluconazole is largely excreted in the urine, forced volume diuresis would probably increase the elimination rate. A three-hour haemodialysis session decreases plasma levels by approximately 50%.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Fluconazole, a member of the triazole class of antifungal agents, is a potent and selective inhibitor of fungal enzymes necessary for the synthesis of ergosterol.

Fluconazole shows little pharmacological activity in a wide range of animal studies. Some prolongation of pentobarbitone sleeping times in mice (p.o.), increased mean arterial and left ventricular blood pressure and increased heart rate in anaesthetised cats (i.v.) occurred. Inhibition of rat ovarian aromatase was observed at high concentrations.

Both orally and intravenously administered fluconazole was active in a variety of animal fungal infection models. Activity has been demonstrated against opportunistic mycoses, such as infections with *Candida* spp. including systemic candidiasis in immunocompromised animals; with *Cryptococcus neoformans*, including intracranial infections; with *Microsporium* spp. and with *Trichophyton* spp. Fluconazole has also been shown to be active in animal models of endemic mycoses, including infections with *Blastomyces dermatitides*; with *Coccidioides immitis*, including intracranial infection and with *Histoplasma capsulatum* in normal and immunocompromised animals.

There have been reports of cases of superinfection with *Candida* Species other than *C. albicans*, which are often inherently not susceptible to fluconazole (e.g. *Candida krusei*). Such cases may require alternative antifungal therapy.

Fluconazole is highly specific for fungal cytochrome P-450 dependent enzymes. Fluconazole 50mg daily given up to 28 days has been shown not to affect testosterone plasma concentrations in males or steroid concentrations in females of childbearing age. Fluconazole 200-400mg daily has no clinically significant effect on endogenous steroid levels or on ACTH stimulated response in healthy male volunteers. Interaction studies with antipyrine indicate that single or multiple doses of fluconazole 50mg do not affect its metabolism.

5.2. Pharmacokinetic properties

The pharmacokinetic properties of fluconazole are similar following administration by the intravenous or oral route. After oral administration fluconazole is well absorbed and plasma levels (and systemic bioavailability) are over 90% of the levels achieved after intravenous administration. Oral absorption is not affected by concomitant food intake. Peak plasma concentrations in the fasting state occur between 0.5 and 1.5 hours post-dose with a plasma elimination half-life of approximately 30 hours. Plasma concentrations are proportional to dose. Ninety percent steady-state levels are reached by day 4-5 with multiple once daily dosing.

Administration of a loading dose (on day 1) of twice the usual daily dose enables plasma levels to approximate to 90% steady state levels by day 2. The apparent volume of distribution approximates to total body water. Plasma protein binding is low (11-12%).

Fluconazole achieves good penetration in all body fluids studied. The levels of fluconazole in saliva and sputum are similar to plasma levels. In patients with fungal meningitis, fluconazole levels in the CSF are approximately 80% of the corresponding plasma levels.

High skin concentrations of fluconazole, above serum concentrations, are achieved in the stratum corneum, epidermis-dermis and eccrine sweat. Fluconazole accumulates in the stratum corneum. At a dose of 50mg once daily, the concentration of fluconazole after 12 days was 73 mg/g and 7 days after cessation of treatment the concentration was still 5.8 mg/g.

The major route of excretion is renal, with approximately 80% of the administered dose appearing in the urine as unchanged drug. Fluconazole clearance is proportional to creatine clearance. There is no evidence of circulating metabolites.

The long plasma elimination half-life provides the basis for single dose therapy for genital candidiasis.

A study compared the saliva and plasma concentrations of a single fluconazole 100mg dose administration in a capsule or in an oral suspension by rinsing and retaining in the mouth for 2 minutes and swallowing. The maximum concentration of fluconazole in saliva after the suspension was observed 5 minutes after ingestion and was 182

times higher than maximum saliva concentration after the capsule, which occurred 4 hours after ingestion. After about 4 hours, the saliva concentrations of fluconazole were similar. The mean AUC (0-96) in saliva was significantly greater after the suspension compared to the capsule. There was no significant difference in the elimination rate from the saliva or the plasma pharmacokinetic parameters for the two formulations.

5.3. Preclinical safety data

Reproductive Toxicity

Increases in foetal anatomical variants (supernumerary ribs, renal pelvis dilation) and delays in ossification were observed at 25 and 50mg/kg and higher doses. At doses ranging from 80mg/kg (approximately 20-60x the recommended human dose) to 320mg/kg embryoletality in rats was increased and foetal abnormalities included wavy ribs, cleft palate and abnormal cranio-facial ossification. These effects are consistent with the inhibition of oestrogen synthesis in rats and may be a result of known effects of lowered oestrogen on pregnancy, organogenesis and parturition.

Carcinogenesis

Fluconazole showed no evidence of carcinogenic potential in mice and rats treated orally for 24 months at doses of 2.5, 5 or 10mg/kg/day. Male rats treated with 5 and 10mg/kg/day had an increased incidence of hepatocellular adenomas.

Mutagenesis

Fluconazole, with or without metabolic activation, was negative in tests for mutagenicity in 4 strains of *S.typhimurium* and in the mouse lymphoma L5178Y system. Cytogenetic studies *in vivo* (murine bone marrow cells, following oral administration of fluconazole) and *in vitro* (human lymphocytes exposed to fluconazole at 1000µg/ml) showed no evidence of chromosomal mutations.

Impairment of Fertility

Fluconazole did not affect the fertility of male or female rats treated orally with daily doses of 5, 10 or 20mg/kg or with parenteral doses of 5, 25 or 75mg/kg, although the onset of parturition was slightly delayed at 20mg/kg p.o. In an intravenous perinatal study in rats at 5, 20 and 40mg/kg, dystocia and prolongation of parturition were observed in a few dams at 20mg/kg and 40mg/kg, but not at 5mg/kg. The disturbances in parturition were reflected by a slight increase in the number of stillborn pups and decrease of neonatal survival at these dose levels. The effects on parturition in rats are consistent with the species specific oestrogen-lowering property produced by high doses of fluconazole. Such a hormone change has not been observed in women treated with fluconazole.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Lactose monohydrate
Maize starch

Silica, colloidal anhydrous
Sodium laurilsulfate
Magnesium stearate
Titanium dioxide, E171
Brilliant blue FCF, E133
Gelatin

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

36 months.

6.4. Special precautions for storage

Do not store above 30°C.

6.5. Nature and contents of container

Transparent or white opaque PVC/PVdC – aluminium blister packs containing 1 capsule.

6.6 Special precautions for disposal

Not applicable

7 MARKETING AUTHORISATION HOLDER

TEVA UK Limited
Brampton Road
Hampden Park
Eastbourne
East Sussex
BN22 9AG
England

8 MARKETING AUTHORISATION NUMBER(S)

PL 00289/0708

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE
AUTHORISATION**

03/04/2006

10 DATE OF REVISION OF THE TEXT

03/04/2006

Patient Information Leaflet

FLUCONAZOLE 150MG CAPSULE

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PIL pl

FLUCONAZOLE 150 MG CAPSULE

PATIENT INFORMATION LEAFLET

Read all of this leaflet carefully because it contains important information for you. This medicine is available without prescription for you to treat a mild illness without a doctor's help. Nevertheless, you still need to use Fluconazole 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.
- You must see your doctor if your symptoms worsen or do not improve.

In this leaflet:

1. Fluconazole; what it is and what it's used for
2. Before you take Fluconazole
3. How to take Fluconazole
4. Possible side effects
5. Storing Fluconazole

The name of your medicine is **Fluconazole 150 mg Capsule**.

- The active ingredient is fluconazole
- Other ingredients are lactose, maize starch, colloidal anhydrous silica, sodium laurilsulfate and magnesium stearate. The capsule shell contains gelatin and the colours brilliant blue (E133) and titanium dioxide (E171).

The Marketing Authorisation holder and company responsible for manufacture is: TEVA UK Limited, Eastbourne BN22 9AG.



1. FLUCONAZOLE; WHAT IT IS AND WHAT IT'S USED FOR

- Each capsule contains 150 mg of fluconazole. Fluconazole belongs to a group of drugs called antifungal agents, and is used to treat infections, such as thrush.
- The product is available in a pack containing 1 capsule.
- Fluconazole is used to treat vaginal thrush and can also be used by your partner if he has thrush on his penis. Thrush is caused by a yeast called *Candida albicans*, which lives problem free in the bodies of many women, but occasionally the natural balance that keeps the yeast under control is disturbed and this results in an infection.

Vaginal Thrush

The most common symptoms are:

- Itching around the outside of the vagina
- Soreness which becomes worse with rubbing and scratching

- A white, non-smelling discharge from the vagina.

Not every woman who has thrush will have all of these symptoms.

To help prevent thrush coming back it is advised that you:

- Wash regularly
- Gently dry yourself, as rubbing and scratching can aggravate thrush
- Avoid tight synthetic clothing
- Wear cotton underwear, stockings and loose fitting clothes
- Avoid perfumed soaps and bath additives
- Change your sanitary protection frequently.

Thrush may be aggravated by sexual intercourse. Thrush is not VD and is not usually passed on by sexual contact. However, thrush can be passed to your partner through sexual intercourse. If your thrush was successfully treated but keeps coming back, it is advised your partner is seen by a doctor.

Penile Thrush (Candidal Balanitis)

It is important to note that only the male partners of affected women should take this medicine.

The most common symptoms are:

- Soreness and redness of the penis
- Tightness of the foreskin
- An abnormal penile discharge.

Not every man who has thrush on his penis will have all of these symptoms.



2. BEFORE YOU TAKE FLUCONAZOLE

Do not take Fluconazole without first consulting your doctor:

- If you are under 16 or over 60 years of age
- If you are allergic to any of the ingredients in Fluconazole 150 mg Capsule or other antifungals and other thrush treatments
- If you are taking the antihistamine terfenadine or the prescription medicine cisapride
- If you are taking any other medication other than the Pill
- If you have had thrush more than twice in the last six months
- If you have any disease affecting your liver or kidneys or if you have had unexplained jaundice
- If you suffer from any other chronic disease or illness
- If you or your partner have had exposure to a sexually transmitted disease

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- If you are unsure about the cause of your symptoms.

Women only:

- If you have abnormal or irregular vaginal bleeding or a blood stained discharge
- If you have vaginal or vulval sores, ulcers or blisters
- If you are experiencing lower abdominal pain or a burning sensation on passing urine
- If you are pregnant, trying to become pregnant or are breast-feeding.

Men only:

- If your sexual partner does not have 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.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Taking Fluconazole with food and drink

This medicine does not interact with alcohol or nicotine and may be taken with or without food, at any time of the day.

Pregnancy and Breast-feeding

- Do not take Fluconazole if you are pregnant, trying to become pregnant or breast-feeding.



3. HOW TO TAKE FLUCONAZOLE

If your doctor has prescribed this medicine, always follow your doctor's instructions. Otherwise, follow the instructions below. If you do not understand these instructions, or you are in any doubt, ask your doctor or pharmacist.

The capsule should be swallowed whole with a drink of water. One capsule is the complete course of treatment.

If you take more Fluconazole than you should

If you (or someone else) swallow a lot of the capsules all together, or if you think a child has swallowed any of the capsules, contact your nearest hospital casualty department or your doctor immediately.

How quickly will the treatment start to work?

- Your condition should begin to clear up within two days. For some women the effect can be noticed in one day
- If after seven days or more, thrush recurs, you can take this medicine again

- If your condition does not improve after one week you should tell your doctor
- If the thrush recurs more than twice within six months, you should see your doctor.



4. POSSIBLE SIDE EFFECTS

Like all medicines, Fluconazole can have side effects.

The most common side effects are:

- Stomach pain
- Diarrhoea
- Wind
- Nausea.

Rarely people have experienced:

- Liver problems
- Headache
- Rash.

As can happen with any medicine, a few people may develop an allergic reaction. If you experience the following, tell your doctor immediately or go to the casualty department at your nearest hospital:

- Difficulty breathing
- Swelling of the lips, face and neck.

The following side effects have also been reported rarely, but may not be directly due to Fluconazole:

- Hair loss
- Skin reactions
- Blood disorders
- Fits.

If you have these or any side effects not mentioned in this leaflet, please tell your doctor or pharmacist.



5. STORING FLUCONAZOLE

Keep Fluconazole out of the reach and sight of children. Do not store above 30°C. Do not transfer the capsule to another container. Do not use Fluconazole after the expiry date on the outer packaging. Return all unused medicines to your pharmacist for safe disposal.

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TEVA
TEVA UK Limited

Labelling

