



PACKAGE LEAFLET: INFORMATION FOR THE USER

**FLUCONAZOLE TABLETS USP
50MG / 100MG / 150MG / 200MG
TAJ PHARMA**

Fluconazole

Please read this leaflet carefully before you start taking this medicine.

Keep this leaflet. You may need to read it again. If you have further questions, please ask your doctor or pharmacist. You must contact a doctor if your symptoms worsen or do not improve within one week. If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

IN THIS LEAFLET

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1. WHAT FLUCONAZOLE IS AND WHAT IT IS USED FOR

Fluconazole, the active ingredient, belongs to a group of medicines called anti-fungal

agents and is used to treat infections caused by fungi and yeasts. The most common cause of fungal infections is yeast called *Candida*.

Fluconazole is used to treat a fungal infection called vaginal thrush (in women) and associated candidal balanitis (in men).

What is vaginal thrush?

Vaginal thrush is caused by tiny yeast called *Candida*. Many women have the yeast living quite happily and problem-free within their bodies. However, the natural balance that keeps *Candida* under control can be upset by other factors, e.g. antibiotics, diabetes, poor general health, the Pill, or damage to vaginal tissues. Then the levels of yeast become too high and thrush develops. The most common symptoms are:

- Itching around the outside of the vagina.
- Soreness which becomes worse with rubbing and scratching. Also the salt in urine can sting the sore tissue.
- A white, non-smelling discharge from the vagina.

Not every woman who has thrush will have all of these symptoms. Some general advice to help stop thrush coming back:

- Wash regularly, but do not wash and dry yourself too harshly.
- Avoid tight clothing.
- Wear cotton underwear and stockings

rather than tights.

- Avoid perfumed soaps, bath additives and vaginal deodorants.

Change your tampon frequently as a blood-soaked tampon can provide ideal conditions for yeast growth.

Sexual intercourse can damage delicate tissue and aggravate thrush.

Vaginal thrush is not "VD", but may be passed on to your partner through intercourse. If your attack of thrush was successfully treated, but keeps coming back, your partner may need to take Fluconazole Tablet himself. If you are unsure why your thrush keeps coming back, or are unsure if your partner has thrush, you or your partner should see a doctor.

What is candidal balanitis?

Candidal balanitis (penile thrush) is caused by yeast called *Candida*. Balanitis is the medical term used to describe inflammation of the end of the penis. The foreskin may also be inflamed.

Thrush can be passed on from your partner through sexual intercourse.

(Thrush is not "VD" - see "What is vaginal thrush?"). The most common symptoms are:

- Soreness, redness and irritation of the penis.
- Tightness of the foreskin.
- A white, non-smelling discharge from the penis.
- Not every man who has candidal balanitis will have all of these symptoms.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE FLUCONAZOLE

Do not take Fluconazole if:

- You are allergic to fluconazole or to any of the other ingredients (See section 6), or to a similar medicine you have taken to treat a fungal infection or thrush. The symptoms may include itching, reddening of the skin or difficulty in breathing.
- You are taking terfenadine or astemizole (antihistamine medicines for allergies), cisapride (used for stomach upsets), pimozone (used for treating mental illness) or quinidine (used for treating heart arrhythmia) or erythromycin (an antibiotic for treating infections).

Warnings and precautions

Talk to your doctor or pharmacist before taking Fluconazole

- if have had thrush more than twice in the last six months
- if have any disease or illness affecting your liver or kidneys or have had unexplained jaundice (yellowing of the skin and whites of the eyes)
- if you suffer from heart disease including heart rhythm problems
- if you have abnormal levels of

potassium, calcium or magnesium in your blood

- if you develop severe skin reactions (itching, reddening of the skin or difficulty in breathing)
- if you 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)
- 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:

- You have any abnormal or irregular vaginal bleeding or a blood stained discharge.
- You have vulval or vaginal sores, ulcers or blisters.

You are experiencing lower abdominal pain or burning on passing urine.

Men only:

- Your sexual partner does not have vaginal thrush.
- You have penile sores, ulcers or blisters.
- You have an abnormal penile discharge

(leakage).

- Your penis has started to smell.
- You have pain on passing urine.

Other medicines and Fluconazole

Tell your doctor or pharmacist **immediately** if you are taking astemizole, terfenadine (an antihistamine for treating allergies) or cisapride (used for stomach upsets) or pimozone (used for treating mental illness) or quinidine (used for treating heart arrhythmia) or erythromycin (an antibiotic for treating infections) as these should not be taken with Fluconazole (see section: "Do not take Fluconazole if you").

There are some medicines that may interact with Fluconazole. Make sure your doctor knows if you are taking any of the following medicines:

- nifedipine, isradipine, amlodipine, felodipine and losartan (for hypertension-high blood pressure)
- rifampicin, rifabutin (antibiotics for infections)
- medicines that thin the blood to prevent blood clots (Warfarin or similar medicines)
- benzodiazepines (midazolam, triazolam or similar medicines) used to help you sleep or for anxiety
- chlorpropamide, glibenclamide, glipizide or tolbutamide (used to

- control diabetes)
- phenytoin, carbamazepine (used for treating fits)
- ciclosporin, everolimus, sirolimus or tacrolimus (to prevent transplant rejection)
- theophylline (used to control asthma)
- zidovudine, also known as AZT, or saquinavir (used in HIV-infected patients)
- prednisone (steroid)
- oral contraceptives
- alfentanil, fentanyl (used as anaesthesia)
- celecoxib, flurbiprofen, naproxen, ibuprofen, lornoxicam, meloxicam, diclofenac (Non-Steroidal Anti-Inflammatory Drugs (NSAID))
- amitriptyline and nortriptyline (used as anti-depressant)
- amphotericin B, voriconazole (anti-fungal)
- cyclophosphamide and vinca alkaloids (vincristine, vinblastine or similar medicines) used for treating cancer
- halofantrine (used for treating malaria)
- statins (atorvastatin, simvastatin and fluvastatin or similar medicines) used for reducing high cholesterol levels
- vitamin A (nutritional supplement)
- methadone (used for pain)

- ivacaftor (used for treating cystic fibrosis)
- amiodarone (used for treating uneven heartbeats 'arrhythmias')
- hydrochlorothiazide (a diuretic)

You should also tell your doctor or pharmacist about any other medicines that you are taking, including medicines obtained without a prescription.

Fluconazole with food and drink

You may take the capsule with or without a meal.

Pregnancy, breast-feeding and fertility

Ask your doctor or pharmacist for advice before taking any medicine.

You should not take Fluconazole if you are pregnant, think you may be pregnant, are trying to become pregnant or breast-feeding.

Driving and using machines

Fluconazole may cause dizziness or seizures. If affects do not drive or use machines.

Fluconazole contains lactose (milk sugar)

This medicine contains a small amount of lactose (milk sugar). If your doctor has told you that you have an intolerance to some sugars, such as lactose, please contact your doctor before taking this medicine.

3. HOW TO TAKE FLUCONAZOLE

Adults aged 16-60 years: The dose is one capsule. Swallow the capsule whole with a drink of water.

Not recommended for use in children under 16 years or adults over 60 years. Consult your doctor if symptoms have not been

relieved within 1 week of taking this medicine.

If symptoms worsen at any time talk to your doctor.

If you take more capsules than you should: Contact your doctor or the nearest hospital as soon as possible.

4. POSSIBLE SIDE-EFFECTS

Like all medicines Fluconazole may sometimes cause side-effects, although not everybody gets them. If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

If you experience any of the following serious allergic reaction (sudden wheeziness, difficulty breathing or tightness in the chest, swelling of the eyelids, face or lips, blisters or red itchy spots on the skin, itch all over the body, sores around the mouth, eyes, nose or genitals, liver disease) to Fluconazole, you should STOP taking the medication and contact your doctor IMMEDIATELY.

Fluconazole may affect your liver. The signs of liver problems include: tiredness, loss of appetite, vomiting, yellowing of your skin or the whites of your eyes (jaundice).

Fluconazole may affect your adrenal glands and the levels of steroid hormones produced. The signs of adrenal problems include: tiredness, muscle weakness, loss of appetite, weight loss, abdominal pain.

If any of these happen, stop taking Fluconazole and tell your doctor immediately.

Other side effects:

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

Common side effects (may affect up to 1 in 10 people) are:

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

Uncommon side effects (may affect up to 1 in 100 people) are:

- reduction in red blood cells which can make skin pale and cause weakness or breathlessness
- decreased appetite
- inability to sleep, feeling drowsy
- fit, dizziness, sensation of spinning, tingling, pricking or numbness, changes in sense of taste
- constipation, difficult digestion, wind, dry mouth
- muscle pain
- liver damage and yellowing of the skin and eyes (jaundice)
- wheals, blistering (hives), itching, increased sweating
- tiredness, general feeling of being

unwell, fever

Rare side effects (may affect up to 1 in 1000 people) are:

- lower than normal white blood cells that help defend against infections and blood cells that help to stop bleeding
- red or purple discoloration of the skin which may be caused by low platelet count, other blood cell changes
- blood chemistry changes (high blood levels of cholesterol, fats)
- low blood potassium
- shaking
- abnormal electrocardiogram (ECG), change in heart rate or rhythm
- liver failure
- allergic reactions (sometimes severe), including widespread blistering rash and skin peeling, severe skin reactions, swelling of the lips or face
- hair loss

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

5. HOW TO STORE FLUCONAZOLE

Keep out of the sight and reach of children. Do not store above 25°C. Do not use your medicine after the expiry date shown on the carton.

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 contains

a) Each tablet contains:

Fluconazole USP	50mg
Excipients	q.s.

b) Each tablet contains:

Fluconazole USP	100mg
Excipients	q.s.

c) Each tablet contains:

Fluconazole USP	150mg
Excipients	q.s.

d) Each tablet contains:

Fluconazole USP	200mg
Excipients	q.s.

Nature and contents of container
PVC/PVDC/Al blisters.

Pack sizes: Blisters: 7, 14, 28, 30, 50, 90, 100 and 500mg modified-release tablets.

Not all pack sizes may be marketed.



7. MANUFACTURED IN INDIA BY:

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