

# Flocazole<sup>®</sup>

## Fluconazole

### Antifungal

#### PACKAGE LEAFLET: INFORMATION FOR THE USER

**Flocazole ® 50mg hard capsules**  
**Flocazole ® 150mg hard capsules**  
**Flocazole ® 200mg hard capsules**  
**Fluconazole**

#### Read all of this leaflet carefully before you start taking this medicine

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- 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:

1. WHAT FLOCAZOLE IS AND WHAT IT IS USED FOR
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#### 1. WHAT FLOCAZOLE IS AND WHAT IT IS USED FOR

Flocazole is one of a group of medicines called "antifungals". The active substance is fluconazole. Flocazole is used to treat infections caused by fungi and may also be used to stop you from getting a candidal infection. The most common cause of fungal infections is a yeast called Candida.

#### Adults

You might be given this medicine by your doctor to treat the following types of fungal infections:

- Cryptococcal meningitis – a fungal infection in the brain.
- Coccidioidomycosis – a disease of the bronchopulmonary system.
- Infections caused by Candida and found in the blood stream, body organs (e.g. heart, lungs) or urinary tract.
- Mucosal thrush - infection affecting the lining of the mouth, throat and denture sore mouth.
- Genital thrush – infection of the vagina or penis.
- Skin infections - e.g. athlete's foot, ringworm, jock itch, nail infection.

You might also be given Flocazole to:

- Stop cryptococcal meningitis from coming back.
- Stop mucosal thrush from coming back.
- Reduce recurrence of vaginal thrush.
- Stop you from getting an infection caused by Candida (if your immune system is weak and not working properly).

#### Children and adolescents (0 to 17 years old)

You might be given this medicine by your doctor to treat the following types of fungal infections:

- Mucosal thrush - infection affecting the lining of the mouth, throat.
- Infections caused by Candida and found in the blood stream, body organs (e.g. heart, lungs) or urinary tract.
- Cryptococcal meningitis – a fungal infection in the brain.

You might also be given Flocazole to:

- Stop you from getting an infection caused by Candida (if your immune system is weak and not working properly).
- Stop cryptococcal meningitis from coming back.

#### 2. BEFORE YOU TAKE FLOCAZOLE

##### Do not take Flocazole if you

- Are allergic (hypersensitive) to fluconazole, to other medicines you have taken to treat fungal infections or to any of the other ingredients of Flocazole. The symptoms may include itching, reddening of the skin or difficulty in breathing.
- Are taking astemizole, terfenadine (antihistamine medicines for allergies).
- Are taking cisapride (used for stomach upsets).
- Are taking pimozide (used for treating mental illness).
- Are taking quinidine (used for treating heart arrhythmia).
- Are taking erythromycin (an antibiotic for treating infections).
- Use in Pregnancy: There are no adequate and well-controlled studies of fluconazole in pregnant women. Available human data do not suggest an increased risk of congenital anomalies following a single maternal dose of 150 mg. A few published case reports describe a rare pattern of distinct congenital anomalies in infants exposed in utero to high dose maternal fluconazole (400-800 mg/day) during most or all of the first trimester. These reported anomalies are similar to those seen in animal studies. If this drug is used during pregnancy or if the patient becomes pregnant while taking the drug, the patient should be informed of the potential hazard to the fetus. (See PRECAUTIONS, Pregnancy)

##### Take special care with Flocazole

##### Tell your doctor if you

- Have liver or kidney problems.
- Suffer from heart disease, including heart rhythm problems.
- Have abnormal levels of potassium, calcium or magnesium in your blood.
- Develop severe skin reactions (itching, reddening of the skin or difficulty in breathing).

##### Taking other medicines

Tell your doctor **immediately** if you are taking astemizole, terfenadine (an antihistamine for treating allergies) or cisapride (used for stomach upsets) or pimozide (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 Flocazole (see section: "Do not take Flocazole if you").

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

- Rifampicin or rifabutin (antibiotics for infections).
- Alfentanil, fentanyl (used as anaesthetic).
- Amitriptyline, nortriptyline (used as anti-depressant).
- Amphotericin B, voriconazole (anti-fungal).
- 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.
- Carbamazepine, phenytoin (used for treating fits).
- Nifedipine, isradipine, amlodipine, felodipine and losartan (for hypertension-high blood pressure).
- Ciclosporin, everolimus, sirolimus or tacrolimus (to prevent transplant rejection).
- Cyclophosphamide, 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.
- Methadone (used for pain).
- Celecoxib, flurbiprofen, naproxen, ibuprofen, lornoxicam, meloxicam, diclofenac (Non-Steroidal Anti-inflammatory Drugs (NSAID)).
- Oral contraceptives.
- Prednisolone (steroid).
- Zidovudine, also known as AZT; saquinavir (used in HIV-infected patients).
- Medicines for diabetes such as chlorpropamide, glibenclamide, glibizide or tolbutamide
- Theophylline (used to control asthma).
- Vitamin A (nutritional supplement).

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

##### Taking Flocazole with food and drink

You can take your medicine with or without a meal.

##### Pregnancy and breast-feeding

##### Teratogenic Effects.

##### Pregnancy Category C:

Single 50 mg tablet use for Vaginal Candidiasis:

There are no adequate and well-controlled studies of Flocazole in pregnant women. Available human data do not suggest an increased risk of congenital anomalies following a single maternal dose of 150 mg.

##### Pregnancy Category D:

All other indications:

A few published case reports describe a rare pattern of distinct congenital anomalies in infants exposed in utero to high dose maternal fluconazole (400-800 mg/day) during most or all of the first trimester. These reported anomalies are similar to those seen in animal studies. If this drug is used during pregnancy, or if the patient becomes pregnant while taking the drug, the patient should be informed of the potential hazard to the fetus. (See WARNINGS, Use in Pregnancy.)

"Human Data"

Several published epidemiologic studies do not suggest an increased risk of congenital anomalies associated with low dose exposure to fluconazole in pregnancy (most subjects received a single oral dose of 150 mg). A few published case reports describe a distinctive and rare pattern of birth defects among infants whose mothers received high-dose (400-800 mg/day) fluconazole during most or all of the first trimester of pregnancy. The features seen in these infants include: brachycephaly, abnormal facies, abnormal calvarial development, cleft palate, femoral bowing, thin ribs and long bones, arthrogryposis, and congenital heart disease. These effects are similar to those seen in animal studies.

"Pre-clinical safety data"

"Animal Data"

Fluconazole was administered orally to pregnant rabbits during organogenesis in two studies at doses of 5, 10, and 20 mg/kg and at 5, 25, and 75 mg/kg, respectively. Maternal weight gain was impaired at all dose levels (approximately 0.25 to 4 times the 400 mg clinical dose based on BSA), and abortions occurred at 75 mg/kg (approximately 4 times the 400 mg clinical dose based on BSA); no adverse fetal effects were observed.

In several studies in which pregnant rats received fluconazole orally during organogenesis, maternal weight gain was impaired and placental weights were increased at 25 mg/kg. There were no fetal effects at 5 or 10 mg/kg; increases in fetal anatomical variants (supernumerary ribs, renal pelvis dilation) and delays in ossification were observed at 25 and 50 mg/kg and higher doses. At doses ranging from 50 to 320 mg/kg (approximately 2 to 8 times the 400 mg clinical dose based on BSA), embryolethality in rats was increased and fetal abnormalities included wavy ribs, cleft palate, and abnormal cranio-facial ossification. These effects are consistent with the inhibition of estrogen synthesis in rats and may be a result of known effects of lowered estrogen on pregnancy, organogenesis, and parturition.

You should not take Flocazole while you are pregnant or breast-feeding unless your doctor has told you to.

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

##### Driving and using machines

When driving vehicles or using machines, it should be taken into account that occasionally dizziness or fits may occur.

##### Important information about some of the ingredients of Flocazole

This medicine contains a small amount of lactose (milk sugar), if you have been told by your doctor that you have intolerance to some sugars, please contact your doctor before taking this medicine.

#### 3. HOW TO TAKE FLOCAZOLE

**Always take your medicine exactly as your doctor has told you.** You should check with your doctor or pharmacist if you are not sure.

Swallow the capsule whole with a glass of water. It is best to take your capsules at the same time each day.

The usual doses of this medicine for different infections are below:

#### Adults

Condition	Dose
To treat cryptococcal meningitis	400 mg on the first day then 200 mg to 400 mg once daily for 6 to 8 weeks or longer if needed. Sometimes doses are increased up to 800 mg
To stop cryptococcal meningitis from coming back	200 mg once daily until you are told to stop
To treat coccidioidomycosis	200 mg to 400 mg once daily from 11 months for up to 24 months or longer if needed. Sometimes doses are increased up to 800 mg
To treat internal fungal infections caused by Candida	800 mg on the first day then 400 mg once daily until you are told to stop
To treat mucosal infections affecting the lining of mouth, throat and denture sore mouth	200 mg to 400 mg on the first day then 100 mg to 200 mg until you are told to stop
To treat mucosal thrush – dose depends on where the infection is located	50 mg to 400 mg once daily for 7 to 30 days until you are told to stop
To stop mucosal infections affecting the lining of mouth, throat	100 mg to 200 mg once daily, or 200 mg 3 times a week, while you are at risk of getting an infection
To treat genital thrush	150 mg as a single dose
To reduce recurrence of vaginal thrush	150 mg every third day for a total of 3 doses (day 1, 4 and 7) and then once a week for 6 months while you are at risk of getting an infection
To treat fungal skin and nail infections	Depending on the site of the infection 50 mg once daily, 150 mg once weekly, 300 to 400 mg once weekly for 1 to 4 weeks (Athlete's foot may be up to 6 weeks, for nail infection treatment until infected nail is replaced)
To stop you from getting an infection caused by Candida (if your immune system is weak and not working properly)	200 mg to 400 mg once daily while you are at risk of getting an infection

#### Adolescents from 12 to 17 years old

Follow the dose prescribed by your doctor (either adults or children posology).

#### Children to 11 years old

The maximum dose for children is 400 mg daily.

The dose will be based on the child's weight in kilograms.

Condition	Daily dose
Mucosal thrush and throat infections caused by Candida – dose and duration depends on the severity of the infection and on where the infection is located	3 mg per kg of body weight (6 mg per kg of body weight might be given on the first day)
Cryptococcal meningitis or internal fungal infections caused by Candida	6 mg to 12 mg per kg of body weight
To stop children from getting an infection caused by Candida (if their immune system is not working properly)	3 mg to 12 mg per kg of body weight

Doctors sometimes prescribe different doses to these. Always take your medicine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

#### Elderly

The usual adult dose should be given unless you have kidney problems.

#### Patients with kidney problems

Your doctor may change your dose, depending on your kidney function.

#### If you take more Flocazole than you should

Taking too many capsules at once may make you unwell. Contact your doctor or your nearest hospital casualty department at once. The symptoms of a possible overdose may include hearing, seeing, feeling and thinking things that are not real (hallucination and paranoid behavior). Symptomatic treatment (with supportive measures and gastric lavage if necessary) may be adequate.

#### If you forget to take Flocazole

Do not take a double dose to make up for a forgotten dose. If you forget to take a dose, take it as soon as you remember. If it is almost time for your next dose, do not take the dose that you missed. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

#### 4. POSSIBLE SIDE EFFECTS

Like all medicines, Flocazole can cause side effects, although not everybody gets them

A few people develop **allergic reactions** although serious allergic reactions are rare. If you get any of the following symptoms, **tell your doctor immediately**.

- Sudden wheezing, difficulty in breathing or tightness in the chest.
- Swelling of eyelids, face or lips.
- Itching all over the body, reddening of the skin or itchy red spots.
- Skin rash.
- Severe skin reactions such as a rash that causes blistering (this can affect the mouth and tongue).

Flocazole 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).

If any of these happen, stop taking Flocazole 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 which affect 1 to 10 users in 100 are listed below:

- Headache.
- Stomach discomfort, diarrhea, feeling sick, vomiting.
- Increases in blood tests of liver function.
- Rash.

Uncommon side effects which affect 1 to 10 users in 1,000 are listed below:

- 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 which affect 1 to 10 users in 10,000 are listed below:

- 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.

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.

#### 5. HOW TO STORE FLOCAZOLE

- Keep out of the reach and sight of children.
- Do not use Flocazole after the expiry date which is stated on the pack after EXP.
- Store below 30°C.

#### 6. FURTHER INFORMATION

##### What Flocazole contains

- The active substance is fluconazole.
- The other ingredients are: Sodium lauryl sulphate, lactose BP, purified talc, colloidal silicon dioxide, maize starch, gelatin cap.

##### What Flocazole 150 mg hard capsules look like and contents of the pack

**Flocazole 50mg Capsules:** Two toned hard gelatin capsule containing a white to off-white powder. The cap is opaque pink and the body is opaque white. The capsule is printed with "Flocazole 50mg" on both parts.

**Flocazole 150mg Capsules:** Hard gelatin capsule containing a white to off-white powder. The cap and the body are opaque pink. The capsule is printed with "FLOCAZOLE 150mg" on both side.

**Flocazole 200mg Capsules:** Two toned hard gelatin capsule containing a white to off-white powder. The cap is opaque pink and the body is opaque white. The capsule is printed with "FLOCAZOLE 200mg" on both parts.

##### Contents of the pack:

- Flocazole 50mg capsules contain 7 capsules/pack
- Flocazole 150mg capsules contain 1 capsule/pack
- Flocazole 200mg capsules contain 7 capsules/pack

#### Marketing Authorization Holder & Manufacturer

##### SPIMACO

Al-Qassim Pharmaceutical Plant  
 Saudi Pharmaceutical Industries &  
 Medical Appliances Corporation  
 Saudi Arabia.

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"Flocazole" is a trade mark  
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##### To report any side effect(s)

- National Pharmacovigilance Centre (NPC):
- o Fax :+966-1-210-7398
- o E-mail: npc.drug@sfd.gov.sa
- o Website: www.sfd.gov.sa/npc

##### This is a medicament

- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacists who sold the medicament.
- The doctor and the pharmacists are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

##### Keep medicaments out of the reach of children

Council of Arab Health Ministers  
 Union of Arab Pharmacists