

Flukas 150 mg

Fluconazole

FORM AND PRESENTATIONS:

FLUKAS 150 mg: capsule 150 mg of Fluconazole: Boxes of 1, 2, 4 or 12 capsules, in PVC/Alu blister.

COMPOSITION : (Per capsule)

	FLUKAS 150 mg
Fluconazole (as base)	150 mg
Excipients :	Lactose monohydrate, sodium lauryl sulfate, pregelatinised starch, talc, anhydrous colloidal silica and magnesium stearate q.s.f. one capsule size 1.

PHARMACOLOGICAL PROPERTIES:

FLUKAS 150 mg is an imidazole derivate agent which has a systemic antifungal effect.

THERAPEUTIC INDICATIONS:

- Acute or recurrent candida vaginal infections. These infections may be suppressed by local treatment.
- Dermatomycoses : Tinea pedis, Tinea corporis, Tinea cruris, candida infections and Onychomycoses (Tinea Unguim).
- Ptyriasis versicolor treatment.

CONTRA INDICATIONS:

- Antecedent of allergy to Fluconazole or to any other imidazole derivatives,
- Pregnancy and nursing women,
- Patients treated with: Astemisole, Terfenadine, Cisapride.

DOSAGE AND MODE OF ADMINISTRATION:

Dosages:

Adults:

- Vaginal Candida infections: a single oral dose of FLUKAS capsule 150 mg.
- Dermatomycosis and candida infection: dosage is usual in a single capsule FLUKAS 150 mg weekly for 2 to 4 weeks. Plantar epidermophytosis (Tinea pedis) can take up to 6 weeks of treatment.

Children:

From 16 years children can be treated by the same doses than recommended for adults.

Old patients :

No dosage adjustment for clearance Creatinine is necessary in the single-dose treatment.

Mode of administration: oral intake.

WARNING AND PRECAUTION OF USE:

Warning:

In the case of overdosage, you must contact the doctor who takes the adequate measures.

Precautions of use:

Children: there isn't enough data to allow the use of fluconazole in children. In patients with hepatic and / or renal diseases, the regularly control of hepatic function is useful. The stop of fluconazole is mandatory when these function become worse. The patient must be informed about the occurrence of symptoms of hepatic insufficiency (tiredness, anorexia, nausea, vomiting, icterus); than the fluconazole

must be immediately stopped and alert the doctor. Specific clinical monitoring is required in patients who have previously submitted a skin reaction associated with the use of fluconazole or other azole derivative. The patient should be informed that in case of occurrence of bullous lesions, fluconazole should be immediately stopped and will have consult a doctor as soon as possible.

FLUKAS 150 mg contains Lactose. Consequently, it is contraindicated in patients with galactosemia, glucose and galactose mal absorption syndrome or lactate deficit (a rare metabolic illness).

Pregnancy and nursing :

The use of Fluconazole is not recommended in pregnancy and nursing women. However, it may be use in pregnant women in the case of severe infection with no other available treatment.

DRUG INTERACTION:

Association contra indicated: Astemisole - terfenadine - cisapride.

Association with caution of use: coumarinic anticoagulants (warfarine) - Sulfamid hypoglycemic - Hydrochlorothiazides - Phenytoïne - Oral Contraceptifs - Rifampicine - Cyclosporine - Theophyllin - Rifabutine - Tacrolimus - Zidovudine.

ADVERSE EFFECTS

- Gastro intestinal symptoms: nausea, vomiting, abdominal pain and diarrhea.
- Allergic skin reaction: Skin rash, anaphylactic reaction, vesicular skin reaction (Stevens-Johnson syndrome, Lyell syndrome).
- Alopecia is exceptionally noted and regress with the stop of fluconazole.
- General effects: headache may be noted with the use of fluconazole
- Hepatic effects: Rising of transaminases which usually regress with the stop of fluconazole. Severe hepatic insufficiency may occur with over dosage of fluconazole.
- Haematological effects: Leucopenia, thrombocytopenia.

CONDITIONS DE DELIVRANCE:

List I, only on medical prescription.

CONDITIONS PARTICULIERES DE CONSERVATION:

To store at a temperature below 30°C.

PRESENTATIONS AND M.A.N° NUMBER:

Specialities	M.A.N°	Presentations
Flukas 150	923 337 3	Box of 1 capsule
Flukas 150	923 337 5	Box of 2 capsules
Flukas 150	923 337 4	Box of 4 capsules
Flukas 150	923 337 6	Box of 12 capsules

This is a drug

- A drug is a specific product agent.
- A drug is a product acting on your health and its use, contrary to prescriptions may be dangerous for you.
- Strictly respect the doctor's prescription and the instructions of use he has prescribed.
- Follow your pharmacist's know this drug ; its indications and contra-indications.
- Do not discontinue the drug intake by yourself during the prescription period.
- Do not repeat the prescription or increase the dosage without consulting your doctor.

KEEP ANY DRUG OUT OF THE REACH OF CHILDREN.