LOITIN 150 mg Capsules
FLUCONAZOLE

COMPOSITION
Each capsule contains:
Active ingredient: Fluconazole (INN).....150 mg
Excipients: Lactose monohydrate, pregelatinised starch, hydrated colloidal silica, sodium lauryl sulphate and magnesium stearate. The composition of the capsule is: gelatin, titanium dioxide (E-171) and quinolein (E-104) and indigo carmine (E-132).

PHARMACEUTICAL FORM AND CONTENT OF THE CONTAINER
LOITIN 150 mg Capsules is presented in capsule form, in blister with 1 capsule.

ACTIVITY
LOITIN 150 mg Capsules (fluconazole), a drug belonging to the new class of antifungal triazoles, is a potent and specific inhibitor of the fungal synthesis of steroles.
Fluconazole's pharmacokinetic properties are similar following oral or i.v. administration.
Oral fluconazole is well absorbed, with plasma levels (and systemic bioavailability) greater than 90% with regard to the levels obtained following i.v. administration. Oral absorption is not affected by the joint administration of food. Peak plasma concentrations in fasting are obtained between 0.5 and 1.5 hours post-dose with a clearance half-life of approximately 30 hours. Plasma concentrations are dose-proportional. 90% of the equilibrium state levels are reached 4 to 5 days after multiple once-daily doses. The administration of a higher dose on the first day, twice that of the regular daily dose, raises plasma levels to 90% of the equilibrium state levels by the second day. The apparent distribution volume is close to total body water. Plasma protein binding is low. The penetration of fluconazole into all the body liquids studied is high. Levels of fluconazole in saliva and sputum are similar to plasma levels, whereas levels above serum concentrations in the stratum corneum, in the dermis and in eccrine sweat are reached. Fluconazole is accumulated in the stratum corneum, and its concentration can be measured from nail samples taken 6 months after the end of treatment. In patients with fungal meningitis, the concentration of fluconazole in the cerebrospinal fluid is approximately 80% of the plasma level.
Clearance is mainly renal, with 80% of the unchanged dose appearing in urine. The clearance of fluconazole is proportional to the clearance of creatinine. There is no evidence of circulating metabolites.
Its long clearance half-life permits a single-dose administration in the treatment of vaginal candidiasis and balanitis by Candida, and once a day in the other mycoses where it is indicated.
Fluconazole is highly specific for cytochrome P-450-dependent fungal enzymes. Fluconazole does not affect the plasma concentrations of testosterone in males or the concentrations of steroids in women of child-bearing age. Interaction studies with antipyrine indicate that fluconazole does not affect its metabolism.

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MARKETING AUTHORIZATION HOLDER:
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INDICATIONS
- Treatment of acute or recurring vaginal candidiasis and prophylaxis to reduce the incidence of recurring vaginal candidiasis (3 or more episodes per year).
- Treatment of dermatomycoses, including infections by tinea pedis, tinea corporis, tinea cruris, tinea ungium (onichomycosis) and Candida dermal infections.
- Treatment of balanitis by Candida.
- Prevention of relapse of oropharyngeal candidiasis in AIDS patients.

CONTRAINDICATIONS
LOITIN 150 mg Capsules is contra-indicated in patients with known hypersensitivity to the drug or to other related triazole compounds.

SPECIAL WARNINGS AND PRECAUTIONS FOR USE
Since hepatic anomalies have developed in some patients treated with LOITIN 150 mg
Capsules (fluconazole), your physician should bear this in mind.

INTERACTIONS
Your physician should always be aware of any treatment you are taking at present.

Consult your physician if you are taking oral antidiabetic medicines containing chlorpropamide, glibenclamide, glipizide or tolbutamide, anticoagulants (warfarin), diuretics such as hydrochlorothiazide, antiepileptics such as phenytoin, contraceptives, antituberculous treatment with rifampicin, post-transplant cyclosporin treatment or treatment with drugs containing theophylline.

WARNINGS

Pregnancy and lactation: LOITIN 150 mg Capsules has not been shown to be harmless in pregnancy. Fluconazole has seldom been given to pregnant women. Adverse effects have been observed in animal foetuses, albeit only at large doses, associated with maternal toxicity. These findings are not deemed important to the use of fluconazole at therapeutical doses.
Nevertheless, administration of the drug should be avoided during pregnancy except in patients with serious or potentially life-threatening fungal infections, if the effect envisaged with the use of LOITIN 150 mg Capsules outweighs the possible risks for the foetus.
The concentrations of fluconazole in the mother's milk are similar to plasma concentrations,
whereby the use of LOITIN 150 mg Capsules is not recommended for breast-feeding mothers.
Effects on ability to drive and use machines: experience with LOITIN 150 mg Capsules (fluconazole) indicates that treatment with this drug is unlikely to affect the patient's capacity to drive or operate machinery.
Use in children: The use of LOITIN 150 mg Capsules is not recommended in this age group.

POSOLOGY AND METHOD OF ADMINISTRATION

n the treatment of Candida vaginitis a single dose of 1 capsule of LOITIN 150 mg Capsules should be given. A single monthly dose of 150 mg may be used to reduce the incidence of recurring vaginal candidiasis. The duration of treatment should be personalised, although it will last between 4 and 12 months.
For the treatment of dermatomycoses, including infections by Tinea pedis, corporis, cruris and Candida infections, a once-daily dose of 50 mg or a weekly dose of 150 mg is recommended. Treatment normally lasts 2 to 4 weeks, although Tinea pedis infections may require a longer treatment period, 6 weeks at most. A weekly dose of 150 mg is recommended for the treatment of Tinea ungium. Treatment should continue until the infected nail is replaced.
A single dose of 1 capsule of LOITIN 150 mg Capsules should be given for the treatment of balanitis by Candida.
For the prevention of relapses of oropharyngeal candidiasis in AIDS patients, once the patient has completed the full primary treatment a weekly dose of 150 mg of fluconazole may be given indefinitely.

Use in kidney failure
When a single dose of LOITIN 150 mg Capsules is given, no adjustments are required.

INSTRUCTIONS FOR THE CORRECT ADMINISTRATION OF THE PRODUCT

No special requirements.

OVERDOSE

In the event of overdose the patient should be treated symptomatically, with vital constants maintained and gastric lavage, if required.
Fluconazole is excreted mainly in urine. Forced diuresis will probably increase the drug's clearance rate. A 3-hour haemodialysis session reduces plasma levels by approximately 50%.
In case of overdose or accidental ingestion, consult the nearest Toxicology Information Service.

UNDESIRABLE EFFECTS

LOITIN 150 mg Capsules are generally well tolerated. The most frequent side effects are gastrointestinal in nature: nausea, abdominal pain, diarrhoea and flatulence. The next most frequent side effect after the gastrointestinal symptoms is exanthema. In very rare cases, anaphylaxis characterised by paleness, generalised pruritus, tachycardia... may appear. Should any side effect other than those described above appear, see your doctor or pharmacist.

STORAGE

Store this medicinal product at room temperature, away from light, heat, and moisture.

SHELF LIFE

This medicinal product should not be used after the expiry date indicated on the packaging.

KEEP ALL MEDICINES OUT OF THE REACH AND SIGHT OF CHILDREN.

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