**INDICATIONS**

Fluconazole is indicated for:

- Acute or recurrent vaginal candidiasis.
- Mucosal Candidiasis
- Treatment of tinea cruris, tinea corporis and pityriasis versicolor and for the treatment of skin candidiasis
- Treatment of oropharyngeal candidiasis (thrush), including those cases in which such disease affects patients having compromised immune function due to malignancies or to acquired immunodeficiency syndrome (AIDS), as well as atrophic oral candidiasis.

**DOSAGE AND ADMINISTRATION**

Most patients of vaginal candidiasis respond to a single dose of Duracan 150 mg capsule, therapy for infections that needs multiple doses should be continued until the clinical parameters and laboratory tests show that mycotic infection has been resolved.

**RENAL IMPAIRMENT**

No adjustments are necessary when a single dose therapy is realized (Vaginal candidiasis). When a repeated-dose therapy is realized in patients affected with renal impairment, the dosage schedule should be adjusted according to the following table:

<table>
<thead>
<tr>
<th>Creatinine clearance (ml/min)</th>
<th>Dosage interval / daily dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt;40</td>
<td>24 hours (normal regimen)</td>
</tr>
<tr>
<td>21 - 40</td>
<td>48 hours or half normal daily dose</td>
</tr>
<tr>
<td>10 - 20</td>
<td>72 hours or one third normal daily dose</td>
</tr>
<tr>
<td>Patients receiving regular hae-modialysis</td>
<td>One recommended dose after each dialysis</td>
</tr>
</tbody>
</table>

**CHILDREN**

Dosage has been not established for children under the age of 16 years. However a dose of 3-6 mg/kg/ day can be used in systemic candidiasis.

**CONTRAINDICATIONS**

Fluconazole is contraindicated in patients with...
known hypersensitivity to triazole compounds or in acute or chronic hepatopathies, or in hepatic insufficiency patients. It is contraindicated in pregnancy and lactation.

**WARNING**
In some patients particularly with serious underlying diseases such as AIDS and cancer, abnormalities of hepatic, renal, hematological function tests have been observed during the treatment with fluconazole. But the clinical significance and relationship to treatment is uncertain. Hepatic function (transaminase etc) must be carefully and frequently checked. The fluconazole therapy should be discontinued if bullous lesions or erythema multiform develop or with AIDS patient who develop an exfoliative cutaneous reactions.

**PRECAUTIONS**
Fluconazole does not alter the ability of the patient to drive cars or to use machines. The concomitant use of fluconazole with other agents like Warfarin, tolbutamide, hydrochlorothiazide, sulphonylureas may increase the plasma concentration of these agents and it is sufficient to adapt the doses to the therapeutic requirements to the mentioned drugs. Fluconazole does not affect the endogenous steroid levels.

**SIDE EFFECTS**
Fluconazole is generally well tolerated, and most reported side effects are correlated to the gastrointestinal tract and they include nausea, abdominal pain, diarrhoea and flatulence. Occasional abnormalities of liver enzymes have been observed.

**DRUG INTERACTIONS**
Concomitant use of rifampicin or theophylline with fluconazole results in reduced fluconazole serum levels. In case of concomitant administration of fluconazole and cyclosporin A, monitoring of plasma concentrations of cyclosporin is advised. No negative effects were observed in the case of simultaneous intake of Fluconazole and oral contraceptives.

**OVERDOSAGE**
In case of accidental overdose, supportive measure and symptomatic treatment with gastric lavage (if necessary) may be adequate, a forced diuresis is likely to increase the excretion percentage, hemodialysis decreases plasma level by 50%.

**PRESENTATION**
Duracan 150 mg: Box containing 1 capsule.

**STORAGE**
Store at 15°C - 25°C. Keep out of the reach of children.