71 mm

220 mm

Rolac® 100mg Capsules
(Itraconazole)

WARNING AND PRECAUTIONS:
Congestive Heart Failure
Itraconazole capsule should not be administered for the treatment of onychomycosis in patients with evidence of ventricular dysfunction such as congestive heart failure (CHF) or a histroy of CHF. If signs and symptoms of congestive heart failure occur during administration of itraconazole capsules, discontinue administration

Drug Interactions
Coadministration of cisapride, pimozide, quinidine, defetilide, or levacetylmethadol (Levomethadyl) with itraconazole capsules is contraindicated. itraconazole, a potent cytochrome P450 3A4 isoenzyme system (CYP3A4) inhibitor, may increase plasma concentrations of drugs metabolized by this pathway. Serious cardiovascular events, including QT prolongation, torsades de pointes, ventricular tachycardia, cardiac arrest, and/or sudden death have been occurred in patients using cisapride, pimozide, levacetylmethadole (Levomethadyl), or quinidine, concomitantly with itraconazole and/or othe CYP3A4 inhibitors

DESCRIPTION:
Rolac© is a systemic broad-spectrum antifungal agent available in capsule form containing 100mg itraconazole for oral administration

COMPOSITION:
Each capsule contains:
Coated pellets of Itraconazole MS
equivalent to Itraconazole 100mg

PHARMACOKINETICS:
Rolac© is well absorbed when given by mouth after a full meal. Mean peak plasma concentrations can be reached within 3 to 4 hours and for a100mg dose, can range from 400 to 600mg per ml at steady state, which can be reached within 1 to 2 weeks. Bioavailability increases with doses of 100 to 400mg in such a manner as to suggest that **Rolac©** undergoes saturable metabolism. **Rolac©** is highly protein bound; only 0.2% circulates as free drug. Concentrations of **Rolac©** in whole blood are 60% of those in plasma. **Rolac©** is widely distributed but only small amounts diffuse into the CSF. Therapeutic concentration of **Rolac©** remains in the skin and mucous membranes for 1 to 4 weeks after the drug is discontinued. **Rolac©** is metabolized in liver to inactive compounds, which are excreted in the bile or urine, 3 to 18% is excreted through feces as unchanged drug
Renal excretion of the parent drug is less than 0.03% of the dose. About 35% of a dose is excreted as metabolites in the urine within 1 week. The half-life of **Rolac©** is reported as 20 hours, increases to 30 hours with continued administration. Elimination from plasma is biphasic with a terminal half-life of 1 to 1.5 days
Therapeutic levels in vaginal tissues are maintained for another 2 days after discontinuation of the 3 days course with 200mg daily and for another 3 days after discontinuation of a 1 day course with 200mg bd

MECHANISM OF ACTION:
As with all azole antifungal agents. **Rolac©** works principally by inhibition of cytochrome P450 14a-demethylase (P45014DM). A major consequence of this interaction is disruption of intracellular membrane and defective formation of the fungal cell membrane with inhibition of lanosterol demethylase leading to accumulation of membrane precursor lipids such as lanosterol

INDICATIONS:
- Dermatophytosis
- Superficial candidosis
- Pityriasis versicolor
- Oculomycoses
- Subcutaneous mycoses
- Systemic mycoses
- Antifungal prophylaxis
- Other infections

DOSAGE:
Various regimes have been found successful; typical doses are listed below (Courses can be repeated and the medication can be continued for months if necessary):

- **Tinea corporis, Tinea cruris**
  200mg daily for one week OR 100mg daily for 2 weeks
- **Tinea pedis, Tinea manuum**
  200mg twice daily for one week OR 100mg daily for 2-4 weeks
- **Vulvovaginal candidiasis**
  200mg twice daily for one day OR 200mg daily for 3 days
- **Oral candidiasis**
  100mg daily for 2 weeks
- **Tinea unguium**
  200mg/day for 6-8 weeks (Fingernails) OR 3-4 months (Toenails)
  200mg twice daily for 7 days, repeated monthly for 2months (Fingernails) OR 3-4 months (Toenails)
- **Blastomycosis and histoplasmosis**
  The recommended dose is 200mg once daily
- **Aspergillosis**
  A daily dose of 200 to 400mg of itraconazole is recommended

The dose in children is usually 5mg per kg body weight per day to maximum 200mg per day but is reserved for exceptional circumstances

OR

As directed by the physician

SIDE EFFECTS:
Rolac© appears to be a relatively safe drug. Side effects, usually minor, are more likely during a prolonged course of treatment. Cases of nausea and vomiting, constipation, headache and dizziness are observed. Abnormal liver function tests are also observed in patients with long-term therapy. Unticaria, endocrine effects including enlarged breasts (In males) and adrenal suppression, tingling in the fingers and toes (Very rare) and congestive heart failure were also observed rarely

Administration in Pregnancy and Lactation
should not be taken in pregnancy although only excreted in tiny amounts from breast milk, a lactating mother should only take it, if it is really essential

Drug Interaction
As **Rolac©** needs acid for its absorption, antacids, H_2 antagonists (Cimetidine, famotidine, ranitidine) and omeprazole should not be taken for 2 hours after **Rolac©**. **Rolac©** increases the concentration of some drugs

Those on **Rolac©** should not take these drugs:

- Cisapride
- HMG Co-A reductase inhibitors (Atorvastatin, lovastatin, simvastatin); fluvastatin and prevastatin are acceptable alternatives
- Midazolam and triazolam
- The antihistamine, astemizole and terfenadine

The dose of these drugs should be reduced:
- Warfarin
- Digoxin
- Methyl prednisolone
- Cyclosporin
- Tacrolimus
- Vinca alkaloids

The dose of these drugs may need reducing if side effects arise:

- Quinidine
- Calcium channel blockers
- Antidiabetic sulphonylurea medication (Tolbutamide, glibenclamide, gliclazide, glipizide)

The following drugs decrease the concentration of **Rolac©**:

- Rifampicin
- Isoniazid
- Phenytoin & carbamazepine

Rolac© is not thought to inactive with the oral contraceptive pill

Acute over - dosage
There are no reports of over-dosage. In the event of accidental overdosage, supportive measures should be employed. Within the first hour after ingestion, gastric lavage may be performed Activated charcoal may be given if considered appropriate. **Rolac©** cannot be removed by haemodialysis. No specific antidote is available

Irreversible adverse effects
No reactions of this kind have been reported

STABILITY:
See expiry on the pack

PRESENTATION:
Rolac© 100mg capsules in a pack of 4's

INSTRUCTIONS:
Keep out of reach of children
Avoid exposure to heat, light and humidity
Store between 15 to 30°C
Improper storage may deteriorate the medicine

رولیک ۱۰۰ ملی گرام کیپسول
(اٹراکونازول)

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں

ہدایات: بچوں کی پہنچ سے دور رکھیں

دوا کو دھوپ، گرمی اور نمی سے محفوظ ۱۵ سے ۳۰ ڈگری سینٹی گریڈ کے درمیان میں رکھیں ورنہ دوا خراب ہو جائیگی

Manufactured by:
SAMI Pharmaceuticals (Pvt.) Ltd.
F-95, S.I.T.E., Karachi-Pakistan
www.samipharmapk.com