

COMPOSITION

Each capsule contains Fosravuconazole L-Lysine Ethanolate INN equivalent to 100 mg of Ravuconazole.

PHARMACOLOGY

Fosravuconazole L-lysine ethanolate is a prodrug of Ravuconazole, a novel triazole antifungal agent, exerting broad and potent antifungal activity. It shows antimycotic effects by inhibiting the biosynthesis of ergosterol, which is a cellular membrane component of fungi. Ravuconazole is structurally more similar to fluconazole and voriconazole, containing a thiazole instead of a second triazole. It is usually used to treat Onychomycosis. Ravuconazole is highly active against all Aspergillus species (including A. fumigatus & A. flavus isolates), Candida spp., Cryptococcus neoformans & other yeasts, including fluconazole-resistant isolates.

INDICATION

Ravu[™] 100 Capsule is indicated for the treatment of Onychomycosis.

DOSAGE & ADMINISTRATION

The usual adult dosage is 1 capsule (100 mg as Ravuconazole) administered orally once daily for a period of 12 weeks.

ADVERSE EFFECT

The most commonly reported adverse reactions include stomach discomfort, constipation and angular cheilitis. If any of these symptoms occur, consult with your doctor. The symptoms described below are rarely seen as initial symptoms of the adverse reactions. If any of these symptoms occur, stop taking this medicine and see your doctor immediately:

- loss of appetite, nausea, jaundice [liver dysfunction]
- Round or oval red rash, fever, joint pain [erythema multiforme]

CONTRAINDICATION

Do not use in cases of known sensitivity (specially generalized allergic reaction) to any of the ingredients.

PRECAUTION

Trim the lesioned nail with a file or nail clipper as necessary. If anyone is capable of becoming pregnant, be sure to use birth control while taking this medicine and for at least 3 months after discontinuing this medicine.

DRUG INTERACTION

The therapeutic efficacy of Ravuconazole can be increased when used in combination with Amiodarone, Amlodipine, Bepridil, Cinnarizine, Clevidipine & Carvedilol. The therapeutic efficacy of Acenocoumarol can be increased when used in combination with Ravuconazole. Cimetidine, Calcium carbonate, Almasilate, Aluminium phosphate, Aluminum hydroxide & Asenapine can cause a decrease in the absorption of Ravuconazole resulting in a reduced serum concentration and potentially a decrease in efficacy.

USE IN PREGNANCY & LACTATION

If anyone is capable of becoming pregnant, be sure to use birth control while taking this medicine and for at least 3 months after discontinuing this medicine.

STORAGE

Store below 30 $^{\circ}$ C, in a dry place. Keep all medicines out of reach of children.

HOW SUPPLIED

 $\mathbf{Ravu}^{\mathbf{m}}$ 100 Capsule: Each box containing 10 capsules in Alu-Alu blister pack.

Manufactured by

