

COMPOSITION

Each tablet contains Rupatadine Fumarate INN equivalent to Rupatadine 10 mg.

PHARMACOLOGY

Rupatadine is a long acting, non-sedating anti-allergic drug which displays strong antagonist activity towards both histamine H₁ receptors and Platelet-Activating Factor (PAF) receptors. PAF induces vasodilation and an increase in vascular permeability, which is responsible for rhinorrhoea and nasal congestion. With dual mode of action, Rupatadine shows better therapeutic efficacy than an isolated antihistamine. In addition, Rupatadine inhibits mast cell degranulation; neutrophil and eosinophil migration and cytokine release, particularly of the tumor necrosis factor alpha (TNF- α) in human mast cells and monocytes. Rupatadine has very little or no CNS activity including sedating effect.

INDICATIONS

Rupatadine is indicated for the symptomatic treatment of seasonal & perennial allergic rhinitis and urticaria.

DOSAGE AND ADMINISTRATION

Adults and adolescents (above 12 years): The recommended dosage is 10 mg (one tablet) once daily, with or without food.

CONTRAINDICATIONS

Hypersensitivity to Rupatadine or to any of the excipients.

WARNING AND PRECAUTION

Administration of a dose of 10 mg daily of Rupatadine has not shown significant effects on the function of the central nervous system as seen in specific studies done for psychomotor function. Nevertheless, the patient should take precaution in driving or managing machines. The administration of Rupatadine with grape fruit juice is not recommended. Use of Rupatadine is not recommended in patients with renal or hepatic insufficiency. As no relevant clinical data is available.

SIDE EFFECTS

The most common undesirable effects occurs somnolence, headache and fatigue. Other common undesirable effects include dizziness, asthenia and increased appetite.

USE IN PREGNANCY AND LACTATION

There is no clinical data available on the exposure of Rupatadine during pregnancy. Pregnant women should therefore not use Rupatadine, unless the potential benefit outweighs the potential risk for the infant. No information is available, whether Rupatadine is excreted in the mother's milk. Therefore, it should not be used during lactation, unless the potential benefits for the mother justify the potential risk to the infant.

USE IN CHILDREN AND ADOLESCENTS

Safety and effectiveness of Rupatadine in patients younger than 12 years have not been established.

DRUG INTERACTIONS

CYP3A4 inhibitors like Erythromycin & Ketoconazole inhibits both the presystemic and systemic metabolism of Rupatadine. Due to this potential interaction, it is not recommended to use Rupatadine in combination with Ketoconazole, macrolides or any other inhibitors of CYP3A4. Coadministration of Rupatadine and CNS depressants or alcohol may increase CNS depressant effect.

OVERDOSAGE

An accidental consumption of very high dose should be treated symptomatically together with the necessary supportive measures.

STORAGE

Store below 30°C temperature in a cool & dry place. Protect from light. Keep out of the reach of children.

HOW SUPPLIED

Each box contains 30 tablets in Alu-Alu blister pack.