

RUFAS

Indications

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

Therapeutic Class

Non-sedating antihistamines

Pharmacology

Rupatadine is a second generation, non-sedating, long-acting histamine antagonist with selective peripheral H₁ receptor antagonist activity. It further blocks the receptors of the platelet-activating factor (PAF) according to in vitro and in vivo studies.

Rupatadine possesses anti-allergic properties such as the inhibition of the degranulation of mast cells induced by immunological and non-immunological stimuli, and inhibition of the release of cytokines, particularly of the tumor necrosis factors (TNF) in human mast cells and monocytes.

Dosage & Administration

Rupatadine Tablet: The recommended dosage is 10 mg once daily, with or without food.

Rupatadine Oral Solution (Children aged 2 to 11 year):

☐ Children weighing 25 kg or more: 1 teaspoonful (5 ml) of oral solution once daily with or without food.

☐ Children weighing equal or more than 10 kg to less than 25 kg: 1/2 teaspoonful (2.5 ml)

oral solution once daily with or without food.

Interaction

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.

Co

administration of Rupatadine and CNS depressants or alcohol may increase CNS depressant effect.

Contraindications

Hypersensitivity to Rupatadine or to any of the excipients.

Side Effects

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

Pregnancy & Lactation

Pregnancy category B2 (by TGA, Australia).

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 fetus. 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.

Precautions & Warnings

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 in Special Populations

Elderly: Rupatadine should be used with caution in elderly. No information is available that indicates the requirement of any dose adjustment in this population.

Children: Neither the safety nor the efficacy of Rupatadine has been established in patients less

than 12 years of age.

Patients with renal or hepatic insufficiency:

Use of Rupatadine is not recommended in patients with renal or hepatic insufficiency. As no relevant clinical data is available.