

# Rupatid

Rupatadine  
10 mg Tablet

Rupatadine is a long-acting, non-sedative antagonist of histamine H<sub>1</sub>-receptors. It also, antagonizes the platelet-activating factor (PAF). Both histamine and PAF causes bronchoconstriction and lead to an increase in the vascular permeability, acting as a mediator in the inflammatory process. This double mechanism of action gives Rupatadine a major clinical efficacy regarding agents that show an isolated antihistamine action. Rupatadine possesses other 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 TNF $\alpha$  in human mast cells and monocytes.

## COMPOSITION

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

## INDICATION

Rupatadine is indicated for the symptomatic treatment of 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.

## CONTRAINDICATION

Hypersensitivity to Rupatadine or to any of the excipients.

## 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.

## SIDE EFFECT

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

## DRUG 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.

## USE IN SPECIAL GROUP

*Pregnancy & 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.

*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.

## STORAGE CONDITION

Keep in a dry place away from light and heat. Keep out of the reach of children.

## HOW SUPPLIED

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

Manufactured by:

**NIPRO JMI Pharma Ltd.**  
Comilla, Bangladesh.

