Rupafen

Rupatadine 10 mg

COMPOSITION
Rupafen Tablet: Each tablet contains Rupatadine fumarate INN equivalent to Rupatadine 10 mg

PHARMACOLOGY
Rupatadine acts as a long-acting, non-sedative antagonist of histamine H_1 receptors and 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 α in human mast cells and monocytes.

PHARMACOKINETICS
Rupatadine is rapidly absorbed after oral administration, with a tmax of approximately 0.75 hours. The mean Cmax was 2.6 ng/mL after a single oral dose of 10 mg and 4.6 ng/mL after a single oral dose of 20 mg. After a dose of 10 mg/day for 7 days, the mean Cmax was 3.8 ng/mL. The elimination half-life was 5.9 hours. The plasma proteins binding rate was 98.5-99 %.

INDICATION
Rupatadine is indicated for the symptomatic treatment of allergic rhinitis and urticaria.

DOSAGE & ADMINISTRATION
Adults and adolescents (above 12 years) - The recommended dosage is 10 mg once daily, with or without food.

CONTRAINDICATION
Hypersensitivity to Rupatadine or to any of the excipients

WARNING & 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.

SIDE EFFECT
The most common undesirable effects associated with rupatadine use in controlled clinical studies were somnolence, headache and fatigue. Other uncommon undesirable effects include dyspepsia & increase appetite.

DRUG INTERACTION
CYP3A4 inhibitors like erythromycin & ketoconazole inhibit 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 PREGNANCY & LACTATION
Use in pregnancy:There is no clinical data available on the exposure of Rupatadine during pregnancy. Studies in animals did not show direct or indirect damaging effects, which refer to the pregnancy, embryonic/fetal development, delivery or pre-natal development. Pregnant women should therefore not use Rupatadine, unless the potential benefit outweighs the potential risk for the infant.
Use in lactation: 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.

PATIENT WITH LIVER OR KIDNEY INSUFFICIENCY
Use of Rupatadine is not recommended for patients who have problems with their liver or kidney function, as no relevant clinical data is available.

STORAGE
- Store in cool & dry place, protect from light
- Keep out of reach of children

PACKAGING
Rupafen Tablet: Each box contains 3x10 tablets in Alu- PVC blister pack.

Manufactured by
SOMATEC PHARMACEUTICALS LTD.
SARULIA, DEMRA, DHAKA, BANGLADESH