# Rupoma

Rupatadine

**Composition**
**Rupoma Tablet:** Each tablet contains Rupatadine 10 mg (as Rupatadine Fumarate INN.)
**Rupoma Oral Solution:** Each 5 ml oral solution contains Rupatadine 5 mg (as Rupatadine Fumarate INN.)

**Pharmacology**
Rupatadine is a long-acting, non-sedative antagonist of histamine $H_1$-receptor. It also antagonizes the platelet-activating factor (PAF). Both histamine and PAF cause bronchoconstriction which leads to an increase in the vascular permeability and act as a mediator in the inflammatory process. 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 tumor necrosis factor alpha (TNFα) in human mastocytes and monocytes.

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

**Dosage and Administration**
**Rupoma Tablet**
Adults and adolescents (over 12 years of age): The recommended dose is 10 mg (one tablet) once a day, with or without food.
**Rupoma Oral Solution**
Children aged 2 to 11 year
Children weighing equal or more than 25 kg: 1 teaspoonful (5 ml) of oral solution once a day, with or without food.
Children weighing equal or more than 10 kg up to less than 25 kg: ½ teaspoonful (2.5 ml) of oral solution once a day, with or without food.

**Contraindications**
Hypersensitivity to Rupatadine or to any of the excipients.

**Side Effects**
The most common undesirable effects are sleepiness, general weakness, fatigue, dry mouth, headache & dizziness.

**Precautions**
The administration of Rupatadine with grapefruit juice is not recommended. Rupatadine should be used with caution in patients with known prolongation of the QT interval, patients with uncorrected hypokalemia, patients with ongoing proarrhythmic conditions, such as clinically significant bradycardia, acute myocardial ischemia.
Rupatadine should be used with caution in elderly patients (65 years and older) due to little clinical data. As there is no clinical experience in patients with impaired kidney or liver function, the use of Rupatadine 10 mg tablets is at present not recommended in these patients.
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.

**Uses 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 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.

**Drug Interactions**
CYP3A4 inhibitors like Ketoconazole or Erythromycin 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 or any other inhibitors of CYP3A4. Co administration of Rupatadine and CNS depressants or alcohol may increase CNS depressant effect.

**Overdose**
No symptoms of over dose have been reported. If they occur, symptomatic treatment should be provided.

**Storage Conditions**
Store in a cool and dry place, away from light. Keep out of reach of children.

**Commercial Pack**
**Rupoma Tablet:** Each box contains 3 blister packs of 10 tablets.
**Rupoma Oral Solution:** Each bottle contains 50 ml oral solution.

Manufactured by:
general GENERAL
Pharmaceuticals Ltd.
Kaliakair, Gazipur, Bangladesh

22060127-V00