Rata

Rupatadine Fumarate

COMPOSITION:

Rata Tablet: Each tablet contains Rupatadine Fumarate INN equivalent to Rupatadine 10 mg.

PHARMACOLOGY:

Rupatadine is a long-acting, non-sedative antagonist of histamine H_1-receptors. 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. With the dual mode of action, Rupatadine shows better therapeutic effect than an isolated antihistamine. 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 (TNF α) in human mastocytes and monocytes.

INDICATION:

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

DOSAGE AND ADMINISTRATION:

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

SIDE EFFECT:

Sleepiness, headache, dizziness, dry mouth, fatigue, asthenia.

CONTRAINDICATION:

Hypersensitivity to Rupatadine or to any of the excipients.

PRECAUTION:

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 or 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.

USE IN PREGNANCY AND LACTATION:

No adequate data available. Caution should be exercised when prescribing rupatadine to pregnant or lactating women; it is unknown whether rupatadine is excreted into breast milk.

DRUG INTERACTION:

The concomitant administration of rupatadine 20 mg and ketoconazole or erythromycin increases the systemic exposure. rupatadine should be used with caution when it is administered concomitantly with these drug substances and other inhibitors of the isozyme CYP3A4. Rupatadine should be used with caution when it is coadministered with statins or CNS depressants or alcohol.

OVERDOSAGE:

No case of overdose has been reported. In a clinical safety study rupatadine at daily dose of 100 mg during 6 years was well tolerated. The most common adverse reaction was somnolence. If accidental ingestion of very high doses occurs symptomatic treatment together with the required supportive measures should be given.

PHARMACEUTICAL PRECAUTION:

It should be stored in a cool and dry place, protected from light and moisture. Should be stored at room temperature below 30°C.

HOW SUPPLIED:

Rata Tablet: Each box contains 3x10 tablets in Alu-Alu blister pack.

Manufactured By:

MEDICON **MEDICON Pharmaceuticals Ltd.**
Mirpur, Dhaka, Bangladesh