

# Rupatrol<sup>®</sup>

Rupatadine 10 mg

## COMPOSITION

**Rupatrol<sup>®</sup>** Tablet: Each tablet contains Rupatadine 10 mg as Rupatadine Fumarate INN.

## PHARMACOLOGY

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 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  $\alpha$ ) in human mastocytes and monocytes.

## INDICATION

Rupatadine is indicated for the symptomatic treatment of Seasonal & Perennial Allergic Rhinitis and Urticaria.

## DOSAGE & ADMINISTRATION

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

## CONTRAINDICATION

Hypersensitivity to Rupatadine or to any of the excipients.

## SIDE EFFECT

Sleepiness, headache, dizziness, dry mouth, asthenia, sensation of weakness and fatigue.

## 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.

## PREGNANCY & 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.

## STORAGE

Store below 30° C, protected from light. Keep out of reach of children.

## HOW SUPPLIED

Manufactured by



**SQUARE**  
PHARMACEUTICALS LTD.  
BANGLADESH