

# Rupaxen

Rupatadine 10 mg

## COMPOSITION:

**Rupaxen tablet:** Each film-coated tablet contains Rupatadine Fumarate BP equivalent to Rupatadine 10 mg.

## DESCRIPTION:

Rupaxen is a preparation of Rupatadine. Rupatadine is a new selective histamine H<sub>1</sub> receptor and platelet-activating factor (PAF) antagonist. Rupatadine has dual mode of action. It acts as a long-acting, non-sedative antagonist at histaminergic H<sub>1</sub>-receptor and also antagonizes the platelet-activating factor (PAF). This dual mode of action gives Rupatadine a major clinical efficacy.

## INDICATIONS:

Rupaxen is indicated for the symptomatic treatment of seasonal & perennial allergic rhinitis and idiopathic urticaria.

## DOSAGE AND ADMINISTRATION:

*Adults and adolescents (above 12 years):* 10 mg (one tablet) once daily, with or without food.

*Elderly (above 65 years):* Rupatadine should be used with caution in elderly. No information is available that indicates the requirement of any dose adjustment for this group of patients.

*Children:* Rupatadine is not recommended in patients less than 12 years of age.

*Patients with renal or hepatic insufficiency:* Not recommended.

## SIDE-EFFECTS:

Rupatadine is usually a non-sedating antihistamine. However, as in other non-sedating second generation antihistamines, the most common side-effects may be somnolence, headache and fatigue.

## CONTRAINDICATIONS:

Rupaxen should not be administered in patients with hypersensitivity to Rupatadine or any of its ingredients.

## USE IN PREGNANCY AND LACTATION:

*Pregnancy:* Pregnancy category B<sub>2</sub>. Available limited data shows no adverse effect of Rupatadine on pregnant mother or the fetus/newborn child. Since data are not sufficient, pregnant women should use Rupatadine if the expected benefits outweigh the potential risk to the mother and the child.

*Lactation:* No information is available, whether Rupatadine is excreted in the mother's milk. Therefore, it should be used during lactation if the potential benefits outweigh the potential risk to the mother and the child.

## DRUG INTERACTIONS:

Inhibitors of CYP3A4 may decrease the metabolism of Rupatadine. As in other anti-histamines, the interactions with CNS depressants cannot be excluded.

## OVERDOSE:

An accidental consumption of very high dose should be treated symptomatically together with the necessary supportive measures.

## STORAGE:

Protect from light. Keep in a dry place at a temperature not exceeding 30°C. Keep out of the reach of children.

## PACKING:

**Rupaxen tablet:** Each box contains 30 tablets in Alu-Alu blister strips.

*Manufactured by:*

**Novatek Pharmaceuticals Ltd.**

Gilarchala, 7 Kewa Mouza, Sreepur, Gazipur, Bangladesh.

**NOVATEK**