

Rupamine

Rupatadine INN

Composition:

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

Rupamine Oral Solution : Each 5 ml solution contains Rupatadine Fumarate INN equivalent to Rupatadine 5 mg.

Description:

Rupamine is a preparation of Rupatadine. Rupatadine is a new selective histamine H1 receptor and platelet-activating factor (PAF) antagonist. Rupatadine has dual mechanism of action. It acts as a long-acting, non-sedative antagonist at histaminergic H1-receptor and also antagonizes the platelet-activating factor (PAF). This dual mechanism of action gives Rupatadine a major clinical efficacy.

Indications and Uses:

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

Dosage and Administration:

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

Contraindications:

Rupamine should not be administered in patients who show hypersensitivity to Rupatadine or any of the excipients.

Precautions:

Rupamine should be used with caution in old patients. Its use is not recommended in patients with renal or hepatic insufficiency, and in children less than 12 years. 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. The administration of rupatadine with grape fruit juice is not recommended.

Side-effects:

The most common undesirable effects associated with rupatadine use in controlled clinical studies were somnolence, headache and fatigue. Other common undesirable effects include dizziness and asthenia.

Use in pregnancy and 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.

Drug Interactions:

CYP3A4 inhibitors like Erythromycin & Ketoconazole 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, macrolides or any other inhibitors of CYP3A4. Co administration of Rupatadine and CNS depressants or alcohol may increase CNS depressant effect.

Commercial Pack:

Rupamine Tablet: Each box contains 3 x 10 tablet in alu-alu blister pack.

Rupamine Oral Solution : Each bottle contains 60 ml solution with a measuring spoon.



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