Duvent®

Rupatadine
Tablet / Oral Solution

Description

Duvent® is the preparation of Rupatadine. Rupatadine is a second generation, non-sedating, long-acting histamine antagonist with selective peripheral H_1 receptor antagonist activity. It further blocks the receptors of the platelet-activating factor (PAF) according to in vitro and in vivo studies. Rupatadine possesses 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 TNF (Tumor necrosis factor) in human mast cells and monocytes.

Indications

Symptomatic treatment of allergic rhinitis and urticaria.

Dosage and Administration

Adults and adolescents (over 12 years of age)
The recommended dose is 10 mg (one tablet) once a day, with or without food.
Dosage in children weighing 25 kg or more:
5 ml (5 mg of Rupatadine) of oral solution once a day, with or without food.
Dosage in children weighing equal or more than 10 kg to less than 25 kg:
2.5 ml (2.5 mg of Rupatadine) of oral solution once a day, with or without food.

Contraindications

Hypersensitivity to Rupatadine or to any of the excipients.

Precautions

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.

Use in Special Population

Use in Elderly
Rupatadine 10 mg Tablets should be used with caution in elderly patients (65 years and older).
Use in Paediatric patients
This medicine is not for use in children under 2 years of age or weighing less than 10 kg.
Use in Patients with renal or hepatic insufficiency
As there is no clinical experience in patients with impaired kidney or liver functions, use of Rupatadine is at present not recommended in these patients.
Use in Pregnancy and Lactation
Caution should be exercised when prescribing Rupatadine to pregnant women.
Due to the lack of human data, caution should be exercised when prescribing Rupatadine to lactating mother.

Adverse Reactions

Common side effects are sleepiness, headache, dizziness, dry mouth, sensation of weakness and fatigue. Uncommon side effects are increased appetite, irritability, difficulty concentrating, nosebleed, nasal dryness, sore throat, cough, dry throat, rhinitis, nausea, abdominal pain, diarrhoea, indigestion, vomiting, constipation, rash, back pain, joint pain, muscle pain, thirst, general discomfort, fever, abnormal liver function test and increased weight.

Drug Interactions

Interaction with ketoconazole or erythromycin:
The concomitant administration of Rupatadine 20 mg and ketoconazole or erythromycin increases the systemic exposure to rupatadine 10 times and 2-3 times respectively.
Interaction with alcohol: A dose of 20 mg increased the impairment caused by the intake of alcohol.
Interaction with CNS depressants: As with other antihistamines, interactions with CNS depressants cannot be excluded.
Interaction with statins: Rupatadine should be used with caution when it is co-administered with statins.

Overdose

No case of overdose has been reported. In a clinical safety study rupatadine at daily dose of 100 mg during 6 days 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 Precautions

Keep out of the reach of children. Keep in a cool & dry place. Protect from light.

Commercial Pack

Duvent® Tablet: Box containing 30 tablets in 3X10's blister strips. Each tablet contains Rupatadine Fumarate INN equivalent to Rupatadine 10 mg.
Duvent® Oral Solution: 50 ml Oral Solution in amber color glass bottle. Each 5 ml contains Rupatadine Fumarate INN equivalent to Rupatadine 5 mg.

BEXIMCO PHARMA

Manufactured by
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