Fixtat™

Bilastine INN

Composition:
Fixtat™ 20 mg Tablet: Each film coated tablet contains Bilastine INN 20 mg.

Pharmacology:
Bilastine is an antihistamine, its effects are mediated via selective inhibition of peripheral H_1 receptors. It shows moderate to high affinity for histamine H_1-receptors and no affinity for muscarinic, serotonergic, dopaminergic and noradrenergic receptors. Bilastine has been demonstrated to have limited distribution to the brain following oral administration.

Indication:
Bilastine is indicated for-

- Allergic Rhinitis
- Allergic Rhinoconjunctivitis
- Urticaria

Dose & Administration:
Adults and adolescents (>12 years): 20 mg **Fixtat**™ tablet once daily.

Route of administration: Oral. **Fixtat**™ tablet should be taken one hour before or two hours after intake of food or fruit juice.

Contraindication:
Hypersensitivity to Bilastine or to any ingredient in the formulation or component of the Tablet.

Warning & precaution:
Efficacy and safety of Bilastine in children under 2 years of age have not been established and should be taken cautiously in case of moderate to severe renal impairment.

Side effects:
Common: Drowsiness, Headache, Abdominal pain / Upper abdominal pain.

Uncommon/ rare: Anxiety, Appetite, asthenia, diarrhea, dry mouth, dyspnea, fever, gastritis, gastrointestinal discomfort, insomnia, nasal complaints, nausea, oral herpes, pruritus, QT interval prolongation, sinus arrhythmia, thirst, tinnitus, vertigo, weight increased etc.

Use in pregnancy & lactation:
No adequate data available. Caution should be exercised when prescribing Bilastine to pregnant or lactating women; it is unknown whether Bilastine is excreted into breast milk.

Use in children & adolescents:
Pediatrics (<12 years of age): The safety and efficacy of Bilastine in children under 12 years of age have not been established.

Drug interactions:
With medicine: Concomitant intake of Bilastine 20 mg and ketoconazole, erythromycin, diltiazem, alcohol, lorazepam may increase plasma levels of Bilastine.

With food: Concomitant intake of Bilastine 20 mg and grapefruit juice decreased Bilastine bioavailability by 30%.

Overdose:
After administration of Bilastine at doses 10 to 11 times the therapeutic dose, the frequency of treatment emergent adverse events was two times higher than with placebo. The adverse reactions most frequently reported were dizziness, headache and nausea. No serious adverse events and no significant prolongation in the QTc interval were reported.

Storage:
Do not store above 30^0 C, protect from light & moisture.

Keep out of reach of children.

Packing:
Fixtat™ 20 mg tablet: Each box contains 3x10 tablets in Alu-Alu blister pack.

TM = Trade Mark

RADIANT PHARMACEUTICALS
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