FEXOMIN

FEXOFENADINE HCL USP

Compositions:
Fexomin 60 mg tablet: Each tablet contains Fexofenadine hydrochloride USP 60 mg. Fexomin 120 mg tablet: Each tablet contains Fexofenadine hydrochloride USP 120 mg. Fexomin 180 mg tablet: Each tablet contains Fexofenadine hydrochloride USP 180 mg. Fexomin 50 ml oral suspension: Each 5 ml contains Fexofenadine hydrochloride USP 30 mg.

Pharmacology:
Fexofenadine hydrochloride is an antihistamine with selective H1-receptor antagonist activity. Both enantiomers of fexofenadine hydrochloride displayed approximately equipotent antihistaminic effects. From examination fexofenadine showed no sedative or other central nervous system effects.

Dosage And Administration:
Fexomin tablet: Seasonal Allergic Rhinitis and Chronic Idiopathic Urticaria: Adults and Children 12 Years and Older: 60 mg twice daily or 120 mg once daily or 180 mg once daily. A dose of 60 mg once daily is recommended as the starting dose in patients with decreased renal function. Children 6 to 11 Years: 30 mg twice daily. A dose of 30 mg once daily is recommended as the starting dose in pediatric patients with decreased renal function. Fexomin Oral suspension: Seasonal Allergic Rhinitis: Children 2 to 11 Years: 30 mg (5 ml) twice daily. For pediatric patients with decreased renal function a dose of 30 mg (5 ml) once daily is recommended as the starting dose. Chronic Idiopathic Urticaria: Children 2 to 11 years: 30 mg (5 ml) Fexofenadine oral suspension twice daily. Children 6 Months to less than 2 years: 15 mg (2.5 ml) Fexofenadine oral suspension twice daily. For pediatric patients with decreased renal function the starting doses of Fexofenadine oral suspension are 30 mg (5 ml) once daily for patients 2 to 11 years of age and 15 mg (2.5 ml) once daily for patients 6 months to less than 2 years of age.

Contraindications:
Fexofenadine is contraindicated in patients with a history of hypersensitivity of fexofenadine to any of the components in this medication.

Warning And Precaution:
Caution should be exercised in elderly patient and patient with decreased renal function.

Side Effects:
Nausea, dyspepsia, drowsiness, dizziness, headache, dysmenorrheal hypersensitivity (rash, urticaria, pruritus), nasopharyngitis, upper respiratory tract infection, myalgia, back pain and pain in extremity.

Use in Pregnancy and Lactation:
Teratogenic Effects: Pregnancy Category C. There are no adequate and well-controlled studies in pregnant women. Fexofenadine hydrochloride should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. It is not known if fexofenadine is excreted in human milk. There are no adequate and well-controlled studies in women during lactation. Because many drugs are excreted in human milk, caution should be exercised when fexofenadine hydrochloride is administered to a nursing woman. The safety and effectiveness of fexofenadine hydrochloride in pediatric patients under 6 months of age have not been established.

Drug Interaction:
Plasma concentrations of Fexofenadine increases when given with Erythromycin or Ketoconazole. Antacid containing Aluminium and Magnesium Hydroxide reduces the absorption of Fexofenadine. Fruit juices including grapefruit may reduce the bioavailability of Fexofenadine and use together should be avoided.

Overdosage:
Seek emergency medical attention in case of overdose. Overdose symptoms may include dry mouth, dizziness, or drowsiness.

Storage:
Store Fexomin tablet & oral suspension at controlled room temperature.

Packing:
Fexomin tablet 60 mg: Each box contains 50 tablets in blister strip. Fexomin tablet 120 mg: Each box contains 30 tablets in blister strip. Fexomin tablet 180 mg: Each box contains 6/10/20/30 tablets in blister strip. Fexomin 50 ml oral suspension: Each bottle contains 50 ml oral suspension.

Manufactured By:
The IBN SINA Pharmaceutical Industry PLC.
Shafipur, Gazipur, Bangladesh.