Fixal®

Fexofenadine Hydrochloride USP

Description: Fexofenadine Hydrochloride (**Fixal®**) is an Antihistamine with selective peripheral H_1-receptor antagonist activity. Fexofenadine does not appear to cross the blood brain barrier.

Mode of action: Fexofenadine (**Fixal®**) blocks the H_1-receptor & thus prevents activation of cells by Histamine in GI tract, large blood vessels & bronchial smooth muscle. This leads to relief of the allergic symptoms. Unlike most other antihistamines, Fexofenadine does not cross Blood Brain Barrier, and therefore, does not cause drowsiness.

Pharmacokinetics: Fexofenadine (**Fixal®**) is rapidly absorbed after oral doses with peak plasma concentrations being reached in 2-3 hours. It is about 60 to 70 % bound to plasma proteins. About 5% of the total doses is metabolised, mostly by the intestinal mucosa, with only 0.5 to 1.5% of the dose undergoing hepatic biotransformation by the cytochrome P450 system. Elimination half-life of about 14 hours has been reported although this may be prolonged in patients with renal impairment. Excretion is mainly in the faeces with only 10% being present in the urine.

Composition: Fixal® 30 mg Tablet: Each film coated tablet contains Fexofenadine Hydrochloride USP 30 mg.
Fixal® 60 mg Tablet: Each film coated tablet contains Fexofenadine Hydrochloride USP 60 mg.
Fixal® 120 mg Tablet: Each film coated tablet contains Fexofenadine Hydrochloride USP 120 mg.
Fixal® 180 mg Tablet: Each film coated tablet contains Fexofenadine Hydrochloride USP 180 mg.
Fixal® Suspension: Each 5 ml contains Fexofenadine Hydrochloride USP 30 mg.

Indications: Seasonal Allergic Rhinitis: Fexofenadine (**Fixal®**) tablets are indicated for the relief of symptoms associated with seasonal allergic rhinitis in adults and children 6 years of age and older. Symptoms treated effectively were sneezing, rhinorrhea, itchy nose/palate/throat, itchy/watery/red eyes.
Chronic Idiopathic Urticaria: Fexofenadine (**Fixal®**) tablets are indicated for treatment of uncomplicated skin manifestations of chronic idiopathic urticaria in adults and children 6 years of age and older.
Fexofenadine Hydrochloride (**Fixal®**) significantly reduces pruritus and the number of wheals.

Dosage & administration: Seasonal Allergic Rhinitis
- *Adults (12 years):* 120 mg once daily or 60 mg twice daily.
- *Children 2 to 11 Years:* 30 mg or 1 tsf twice daily.
- *Children 6 months to < 2 years:* 15 mg or $^1/_2$ tsf twice daily.

Chronic Idiopathic Urticaria
- *Adults (12 years):* 180 mg once daily.
- *Children 2 to 11 Years:* 30 mg or 1 tsf twice daily.
- *Children 6 months to < 2 years:* 15 mg or $^1/_2$ tsf twice daily.

Contraindications: Fexofenadine HCl is contraindicated in patients with known hypersensitivity to any of its ingredients.

Side effects: The incidence of adverse events, including drowsiness, is not dose related and is similar across subgroups defined by age, gender, and race. The other side effects are Viral infection (cold, flu), nausea, dysmenorrhea, fatigue, headache and throat irritation.

Use in pregnancy and lactation: There are no adequate and well controlled studies in pregnant women. Fexofenadine 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 is administered to a nursing woman.

Precautions: The carcinogenic potential of fexofenadine was assessed using terfenadine studies with adequate fexofenadine exposure (based on plasma area-under-the-concentration vs. time [AUC] values). No evidence of carcinogenicity was observed in an 18-month study in mice and in a 24-month study in rats at oral doses up to 150 mg/kg of terfenadine (which led to fexofenadine exposures that were approximately 3 and 5 times the exposure at the maximum recommended daily oral dose of fexofenadine hydrochloride in adults [180 mg] and children [60 mg] respectively).

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

Over dosage: Dizziness, drowsiness, and dry mouth have been reported with fexofenadine hydrochloride overdose. Single doses of fexofenadine hydrochloride up to 800 mg (6 healthy subjects at this dose level), and doses up to 690 mg twice daily for 1 month (3 healthy subjects at this dose level) or 240 mg once daily for 1 year (234 healthy subjects at this dose level) were administered without the development of clinically significant adverse events as compared to placebo.

Storage: Keep out of reach of children. Store in a dry place, below 25°C temperature and protected from light.

Packaging: Fixal® 30 mg Tablet: Each carton contains 10X5 tablets in Alu-PVC blister.
Fixal® 60 mg Tablet: Each carton contains 10X3 tablets in Alu-PVC blister.
Fixal® 120 mg Tablet: Each carton contains 10X5 tablets in Alu-PVC blister.
Fixal® 180 mg Tablet: Each carton contains 10X3 tablets in Alu-PVC blister.
Fixal® Suspension: Each bottle contains 50 ml suspension.

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Ideas for healthcare

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