Alafree

Fexofenadine Hydrochloride

Composition
Alafree 120: Each film coated tablet contains Fexofenadine Hydrochloride USP 120 mg.
Alafree Suspension: Each 5 ml suspension contains Fexofenadine Hydrochloride USP 30 mg.

Pharmacology
Fexofenadine Hydrochloride is an antihistamine with selective peripheral H1-receptor antagonist activity. Fexofenadine 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 metabolized, 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 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. Fexofenadine does not appear to cross the Blood-Brain Barrier.

Indication
Seasonal Allergic Rhinitis: Alafree tablet are indicated for the relief of symptoms associated with seasonal allergic rhinitis in adults and children 6 years of age and older. Alafree suspension is indicated for the relief of symptoms associated with seasonal allergic rhinitis in children 2 to 11 years of age. *Symptoms to treat effectively:* sneezing, rhinorrhea, itchy nose/palate/throat, itchy/watery/red eyes. *Chronic Idiopathic Urticaria:* Alafree tablets are indicated for treatment of uncomplicated skin manifestations of Chronic Idiopathic Urticaria in adults and children 6 years of age and older. Alafree suspension is indicated for treatment of uncomplicated skin manifestations of Chronic Idiopathic Urticaria in children 6 months to 11 years of age. Fexofenadine Hydrochloride significantly reduces pruritus and the number of wheals.

Dosage & Administration

Age group	Alafree Tablet	Alafree Suspension
Adults and Children 12 years and older	120 mg once daily with water	---
Children 6 to 11 years	---	30 mg (5 ml) twice daily
Children 2 to 5 years	---	30 mg (5 ml) twice daily
Children 6 months to less than 2 years	---	15 mg (2.5 ml) twice daily

For patients with decreased renal function, care should be taken in dose selection Or as directed by the physician.

Contraindication
Patients with known hypersensitivity to Fexofenadine and any of the ingredients of Alafree.

Precaution
This drug is known to be substantially excreted by the kidney and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection and it may be useful to monitor renal function. Initial doses of Fexofenadine Hydrochloride in patients with renal impairment should be reduced to 60 mg once daily.

Side Effects
The most common side effects in subjects age 12 years and older were headache, back pain, dizziness, stomach discomfort. In subjects aged 6 to 11 years, cough, upper respiratory tract infection, pyrexia and otitis media were more frequently reported. In subjects aged 6 months to 5 years, vomiting, diarrhea, fatigue and rhinorrhea were more frequently reported.

Use in Pregnancy & 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. Caution should be exercised when Fexofenadine is administered to lactating mother.

Use in Children & Adolescents
The safety and efficacy of Fexofenadine for the treatment of allergic rhinitis in children younger than 2 years of age and Chronic Idiopathic Urticaria in infants less than 6 months of age has not been established.

Drug Interaction
Plasma concentrations of Fexofenadine have been increased 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.

Overdose
Reports of Fexofenadine Hydrochloride overdose have been infrequent and contain limited information. However, dizziness, drowsiness and dry mouth have been reported. In the event of overdose, consider standard measures to remove any unabsorbed drug.

Storage
Keep away from light & moisture and store below 30° C. Keep out of the reach of children.

Packing
Alafree 120: Each box contains 3 x 10's tablet in blister pack.
Alafree Suspension: Each box contains a bottle of 50 ml suspension.

Apex™
A Syed Manzur Elahi Enterprise

Manufactured by
Apex Pharma Limited
Shafipur, Kaliakair, Gazipur, Bangladesh