



Alafree

Fexofenadine Hydrochloride

120 mg &
180 mg Tablet

COMPOSITION

Alafree 120: Each film coated tablet contains Fexofenadine Hydrochloride USP 120 mg.

Alafree 180: Each film coated tablet contains Fexofenadine Hydrochloride USP 180 mg.

DESCRIPTION

Alafree (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 cyto-chrome 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 tablets 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. **Alafree** significantly reduces pruritus and the number of wheals.

DOSAGE AND ADMINISTRATION

| Age group | Alafree Tablet | In case of decreased renal function |
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| Adults and Children 12 years and older | 120 mg once daily or 180 mg once daily | 60 mg once daily is recommended as the starting dose |
| Children 6 to 11 years | 60 mg once daily | 30 mg once daily is recommended as the starting dose |

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 whether Fexofenadine is excreted in human milk or not. Caution should be exercised when Fexofenadine is administered to a nursing woman.

SIDE EFFECTS

Fexofenadine is generally well tolerated. Dizziness, headache, stomach upset, back pain may occur.

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 grapesfruit may reduce the bioavailability of Fexofenadine and use together should be avoided.

CONTRAINDICATION

Fexofenadine is contraindicated in patients with known hypersensitivity to any of the ingredients.

STORAGE CONDITION

Tablet: Store at a cool and dry place, protected from light & moisture.
Keep out of the reach of children.

HOW SUPPLIED

Alafree 120: Each box contains 5 x 10 tablets in blister pack.

Alafree 180: Each box contains 3 x 10 tablets in blister pack.



Manufactured by
Apex Pharma Ltd.
Shafipur, Gazipur