Alfex

Fexofenadine Hydrochloride

COMPOSITION:

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

PHARMACOLOGY:

Fexofenadine is a second-generation, long lasting H1-receptor antagonist which has a selective and peripheral H1-antagonistic action. Fexofenadine blocks the H1-receptor and thus prevents activation of cells by histamine in the GI tract, large blood vessels and bronchial smooth muscle. This leads to relief of the allergic symptoms. Unlike most other antihistamines, Fexofenadine does not enter into the brain from the blood and therefore, does not cause drowsiness. Fexofenadine lacks the cardio toxic potential, since it does not block the potassium channel involved in repolarization of cardiac cells.

INDICATION:

It is indicated for the relief of symptoms associated with seasonal and perennial allergic rhinitis and chronic idiopathic urticaria.

DOSAGE AND ADMINISTRATION:

Adults: Allergic rhinitis: 120 mg once daily or 60 mg twice daily and Urticaria: 180 mg once daily.
Children: 2-11 years: 30 mg (1 spoonful) or 5 ml twice daily and 6 months-2 years: 15 mg (1/2 spoonful) or 2.5 ml twice daily.

CONTRAINDICATION:

Fexofenadine is contraindicated in patients with a known hypersensitivity to Fexofenadine or any of its ingredients.

WARNING & PRECAUTION:

Studies in the elderly, patients with hepatic impairment and patients with cardiac disease exposed to Fexofenadine showed no statistically significant differences compared to healthy individuals. As with most new drugs there is only limited data in the elderly and renally or hepatically impaired patients. Fexofenadine should be administered with care in these special groups.

SIDE EFFECT:

Fexofenadine is generally well tolerated. The most commonly reported adverse events are headache, drowsiness, nausea, and dizziness. The incidence of these events observed with Fexofenadine was similar to that observed with placebo.

USE IN PREGNANCY AND LACTATION:

In pregnancy*:* Pregnancy Category B. 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.
Lactation: It is not known if Fexofenadine is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Fexofenadine is administered to a nursing woman.

OVERDOSAGE:

In case of an overdose, standard measures to remove any unabsorbed drug should be employed. Symptomatic and supportive treatment is recommended. There has been no reported case of an acute overdose of Fexofenadine.

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STORAGE:

Store in a cool and dry place (below 30°C), protected from light and moisture. Keep out of reach of children.

PACKING:

Alfex 120 Tablet**:** Each box contains 3 x10 tablets in blister pack.

Alfex Suspension**:** Each bottle contains 50 ml suspension with a measuring spoon.

Manufactured by:

MEDICON Pharmaceuticals Ltd.
Mirpur, Dhaka, Bangladesh