Fenaxo

Fexofenadine Hydrochloride USP

Composition:

Fenaxo-60 Tablet: Each film coated tablet contains Fexofenadine Hydrochloride USP 60 mg.
Fenaxo-120 Tablet: Each film coated tablet contains Fexofenadine Hydrochloride USP 120 mg.
Fenaxo-180 Tablet: Each film coated tablet contains Fexofenadine Hydrochloride USP 180 mg.
Fenaxo Suspension: Each 5 ml suspension contains Fexofenadine Hydrochloride USP 30 mg.

Description:

Fexofenadine is a pharmacologically active metabolite of Terfenadine, a non-sedating antihistamine. It is a second-generation, long lasting H_1 receptor antagonist which has a selective peripheral H_1 antagonistic action. Fexofenadine blocks the H_1 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 cardiotoxic potential, since it does not block the potassium channel involved in repolarization of cardiac cells.

Fexofenadine (Fenaxo) 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 dose is metabolized, mostly by the intestinal mucosa, with only 0.5% to 1.5% of the dose undergoing hepatic biotransformation by the cytochrome P_{450} 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.

Indication:

- Seasonal Allergic Rhinitis: It is indicated for the relief of symptoms associated with seasonal allergic rhinitis in adults and children 2 years of age and older. Symptoms treated effectively were sneezing, rhinorrhea, itchy nose/palate/throat, itchy/watery/red eyes.
- Chronic Idiopathic Urticaria: It is indicated for treatment of uncomplicated skin manifestations of chronic idiopathic urticaria in adults and children 6 months of age and older.
- Fexofenadine Hydrochloride significantly reduces pruritus and the number of wheals.

Dosage & Administration:

Adults:

Seasonal Allergic Rhinitis: 120 mg once daily or 60 mg twice daily.
Chronic Idiopathic Urticaria: 180 mg once daily

Children:

2-11 years: 30 mg (1 tea-spoonful) or 5 ml twice daily.
6 months-2 years: 15 mg (1/2 tea-spoonful) or 2.5 ml twice daily.

Contraindication:

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

Side-effect:

Fexofenadine is generally well-tolerated. The reported adverse events are headache, fatigue, drowsiness, nausea, throat irritation, dizziness, tachycardia, palpitations, dry mouth, nose and/or throat, dyspepsia and gastrointestinal disturbances (including diarrhea). The rare events are taste disturbances, anaphylactic reactions, dyspnea, chest tightness, increased hair loss/hair thinning, photosensitivity, dysmenorrhea, menstrual disorders. As with other non-sedating antihistamines, dizziness, nervousness, agitation, sleep disorders, insomnia or paroniria may infrequently be reported by patients. The incidence of such reports under Fexofenadine was similar to the incidence under placebo.

Effects on ability to drive and use machine:

On the basis of the pharmacodynamic profile and reported adverse events, it is unlikely that Fexofenadine Hydrochloride tablet will produce an effect on the ability to drive or use machinery. In objective tests, Fexofenadine Hydrochloride has been shown to have no significant effects on central nervous system function. This means that patients may drive or perform tasks that require concentration. Fexofenadine did not cross the blood brain barrier in animal studies.

Use in Pregnancy:

It is a drug of pregnancy category-C. Fexofenadine should be used in pregnancy only if the potential benefit outweighs the potential risk to the fetus.

Special Risk Groups:

Studies in special risk groups (elderly, renally or hepatically impaired patients) indicate that it is not necessary to adjust the dose of Fexofenadine Hydrochloride in these patients.

Drug Interactions:

Fexofenadine Hydrochloride at doses of 120 mg twice daily has been safely co-administered with erythromycin (500 mg three times daily) and ketoconazole (400 mg once daily) under steady state conditions in healthy volunteers. An increase in the level of Fexofenadine in plasma of 2 times was observed after co-administration of erythromycin or ketoconazole but this was not associated with any increase in adverse event or effects on the QT interval, compared to that seen when the drugs were given singly. 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.

Overdose:

Dizziness, drowsiness, and dry mouth have been reported with Fexofenadine Hydrochloride overdose. Single doses of Fexofenadine Hydrochloride up to 800 mg and doses up to 690 mg twice daily for 1 month or 240 mg once daily for 1 year were studied in healthy subjects without the development of clinically significant adverse events as compared to placebo.

Storage:

Keep in a cool, dry place, away from light and moisture. Keep away from reach of children.

How Supplied:

Fenaxo-60 Tablet: Each box contains 3 blister strips of 10 tablets.
Fenaxo-120 Tablet: Each box contains 3 blister strips of 10 tablets.
Fenaxo-180 Tablet: Each box contains 2 blister strips of 10 tablets.
Fenaxo Suspension: Each bottle contains 50 ml suspension and a measuring spoon.

KEMIKO

Manufactured by:
KEMIKO PHARMACEUTICALS LTD.
Bangladesh