Telfadin

Fexofenadine Hydrochloride USP

Composition
Telfadin 120 Tablet: Each film coated tablet contains Fexofenadine Hydrochloride USP 120 mg.
Telfadin 180 Tablet: Each film coated tablet contains Fexofenadine Hydrochloride USP 180 mg.
Telfadin 50 ml 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 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.

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

Dose and Administration
Route of administration: Oral
Adults:
Allergic rhinitis: 120 mg once daily or 60 mg twice daily
Urticaria: 180 mg once daily
Children:
2-11 years: 30 mg (1 spoonful) or 5 ml twice daily
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 Hydrochloride should be administered with care in these special groups.

Side Effects
Common: 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 Hydrochloride was similar to that observed with placebo.
Rare: No adequate data are available.

Use in Pregnancy and Lactation
In pregnancy: Pregnancy Category C. 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.

Use in Children & Adolescents
Not recommended for children below 6 months of age.

Drug Interactions
With Medicine: Caution should be taken during the concomitant use of Fexofenadine Hydrochloride with the following drugs: erythromycin, ketoconazole and antacid containing aluminium and magnesium hydroxide gels.
With food & others: No adequate data are available.

Overdose
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 Hydrochloride.

Storage
Store below 30° C temperature. Keep in a cool and dry place, away from light. Keep out of the reach of children.

Packing
Telfadin 120 Tablet: Each box contains 3 blister of 10 tablets.
Telfadin 180 Tablet: Each box contains 2 blister of 10 tablets.
Telfadin 50 ml Suspension: Each bottle contains 50 ml suspension with a measuring cup.

Manufactured by
ONE PHARMA LTD.
C-23-24, BSCIC I/A
Bogura, Bangladesh

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