

### COMPOSITION:

**FD-120** Tablet: Each film-coated tablet contains Fexofenadine Hydrochloride USP 120 mg.

#### **DESCRIPTION:**

Fexofenadine Hydrochloride is an antihistamine with selective peripheral H<sub>1</sub>-receptor antagonist activity. Both enantiomers of Fexofenadine Hydrochloride displayed approximately equipotent antihistaminic effects. It inhibits histamine release from peritoneal mast cells. No sedative or other central nervous system effects were observed. Fexofenadine dose not cross the blood-brain barrier (BBB).

#### INDICATIONS:

Seasonal allergic rhinitis in adults and children of 6 years of age and older. Symptoms treated effectively are sneezing, rhinorrhea, itchy nose/palate/throat, itchy/watery/red eyes. Skin manifestations of chronic idiopathic urticaria in adults and children of 6 years of age and older. It also significantly reduces pruritus and the number wheals and flare.

### DOSAGE AND ADMINISTRATION:

Seasonal Allergic Rhinitis and Chronic Idiopathic Urticaria:

Adults & children 12 years and older: The recommended dose of Fexofenadine Hydrochloride is 60 mg twice daily or 120 mg once daily or 180 mg once daily with water. A dose of 60 mg once daily is recommended as the starting dose in patients with decreased renal function

#### **CONTRA-INDICATIONS:**

Known hypersensitivity to any of its components.

#### SIDE EFFECT:

Adverse effects with Fexofenadine treatment are almost similar to placebo treated patients. The adverse effects that may be observed are headache, dyspepsia, fatigue, drowsiness, dizziness, nausea, chest tightness, dyspnoea etc.

# USE IN PREGNANCY & LACTATION:

There are no adequate and well-controlled studies in pregnancy & nursing woman. Fexofenadine should be used during pregnancy & lactation only if the potential benefit justifies the potential risk to the fetus & baby.

# DRUG INTERACTION:

Plasma concentration levels of Fexofenadine have been increased when co-administered with Erythromycin & Ketoconazole. Antacid containing Aluminium & Magnesium Hydroxide reduces the absorption of Fexofenadine.

## PRECAUTION:

Because of limited data available in the elderly and renally or hepatically impaired patients, Fexofenadine should be administered with care in these special groups.

## PACKING:

 $\mbox{{\bf FD-120}}$  Tablet: Each box contains 3 x 10's Tablets in blister strips.

