



FEXADYNE-120

Fexofenadine Hydrochloride USP

PRESENTATION :

FEXADYNE-120 tablets : Each tablet contains Fexofenadine Hydrochloride USP 120 mg.

PHARMACOLOGY:

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 are 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 AND USES:

Seasonal allergic rhinitis:

FEXADYNE-120 is indicated for the relief of symptoms associated with seasonal allergic rhinitis in adults and children 2 years of age and older symptom treated effectively including sneezing rhinorrhea itchy and watery nose and throat it is skin and red eyes.

Chronic idiopathic Urticaria:

FEXADYNE-120 is also indicated for the treatment of uncomplicated skin manifestations of chronic idiopathic urticaria in adults and children 6 months to 11 years of age.

DOSES AND ADMINISTRATION:

Seasonal allergic rhinitis:

Adults and Children 12 years and older: The recommended dose of FEXADYNE is 60 mg twice daily or 120 mg or 180 mg once daily. A dose of 60 mg once daily is recommended as the starting dose in patients with decrease renal function.

Children 6 to 11 years: The recommended dose of FEXADYNE is 30 mg twice daily. A dose of 30 mg once daily is recommended as the starting dose in pediatric patients with decreased renal function.

Chronic Idiopathic Urticaria:

Adults and Children 12 years and older: The recommended dose of FEXADYNE is 60 mg twice daily or 120 mg or 180 mg once daily. A dose of 60 mg once daily is recommended as the starting dose in patients with decrease renal function.

Children 6 to 11 years: The recommended dose of FEXADYNE is 30 mg twice daily. A dose of 30 mg once daily is recommended as the starting dose in pediatric patients with decreased renal function.

SIDE EFFECTS:

The incidence of adverse events including drowsiness, is not dose related and is similar across subgroups defined by age, gender and race. The other side effects are Viral like infection (cold, flu), nausea, dysmenorrhoeal, fatigue, headache and throat irritation.

DRUG INTERACTION:

FEXADYNE should not be taken closely in time with Aluminium and Magnesium containing antacid, Erythromycin or Ketoconazole co- administration may enhance Fexofenadine absorption.

CONTRAINDICATION:

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

PREGNANCY:

There are no adequate and well controlled studies in pregnant women. FEXADYNE should be used during pregnancy only if the potential benefit justifies the potential risks to be fetus

NURSING MOTHERS:

No adverse effect have been seen in breastfeeding infant whose mother were receiving Fexofenadine Hydrochloride and The American academy of pediatrics considers that it is therefore usually compatible with breastfeeding.

PEDIATRIC USE:

Safety and effectiveness of Fexofenadine Hydrochloride in paediatric patients can be used up to the age of 6 months.

STORAGE:

Store in a cool and dry place, away from light and children.

COMMERCIAL PACK:

FEXADYNE-120 Tablets : Each box containing 2 x 10's, 5 x 10's in Alu-PVC blister strips.



Manufactured by:
Arges Life Science Limited
18/50, Sagorika Road,
Chattogram, Bangladesh.