Rafex®

Fexofenadine

COMPOSITION:

Rafex ® 120 ablet: Each film coated tablet contains Fexofenadine Hydrochloride USP 120 mg.

Rafex ® 50 ml suspension: Each 5 ml suspension contains Fexofenadine Hydrochloride USP 30 mg.

PHARMACOLOGY:

Rafex ® (Fexofenadine) 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 cytochrome P450 system. Elimination half-life of 14 hours has been reported although this may be prolonged in patients with renal impairment. Excretions mainly in the faeces, only 10% being present in the urine. Fexofenadine does not appear to cross the blood-brain barrier.

INDICATION:

Seasonal Allergic Rhinitis & Chronic Idiopathic Urticaria.

DOSE & ADMINISTRATION:

Adults and Children 12 years and older: The recommended dose is 60 mg twice daily or 120 mg once daily or 180 mg once daily. A dose of 60 mg once daily is recommended as the starting dose in patients with decreased renal function. Children 6 to 11 years: The recommended dose is 30 mg twice daily. A dose of 30 mg once dally is recommended as the starting dose in pediatric patients with decreased renal funciion. OR AS DIRECTED BY THE PHYSICIAN.

CONTRA-INDICATION:

Fexofenadine or any ingredients of it is contraindicated in patients with known hypersensitivity.

WARNING AND PRECAUTION:

Fexofenadine should be used with caution in prostatic hypertrophy, urinary retention, susceptibility to angle-closure glaucoma, pyloroduodenal obstruction, hepatic disease & caution may be required in epilepsy.

SIDE EFFECTS:

Drowsiness, headache, psychomotor impairment, and antimuscarinic effects such as urinary retention, dry mouth, blurred vision and gastro-intestinal disturbances may occur. Other rare side-effects of antihistamines include hypotension, palpitation, arrhythmias, extrapyramidal effects, dizziness, confusion, depression, sleep disturbances, tremor, convulsions, hypersensitivity reactions, blood disorders, liver dysfunction, and angle-closure glaucoma.

USE IN PREGNANCY & LACTATION:

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. Itis not known if Fexofenadine is excreted in human milk. Caution should be exercised when Fexofenadine is administered to a nursing woman.

USE IN CHILDREN & ADOLESCENTS:

Fexofendine tablet is not recommended for children below 6 years of age. Fexofenadine oral suspension is recommended for prescription use in 6 months and older and use in 2 years and older.

DRUG INTERACTION:

Plasma concentrations of Fexofenadine have been increased when given with Erythromycin or Ketoconazole. Antacid containing Aluminium and Magnesium Hydroxide reduces 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. In the event of overdose, consider standard measures to remove any unabsorbed drug. Symptomatic and supportive treatment is recommended.

STORAGE:

Store in a dry and cool place below 30^0 C temperature and keep away from light and moisture. Keep out of reach of children.

PACKING:

Rafex ® 120 Tablet: Each box contains 5x10's tablets in blister pack.

Rafex ® 50 ml Suspension: Each bottle containing 50 ml suspension with a measuring cup.

Manufactured by

Team Pharmaceuticals Ltd.

B 75-79, BSCIC, Sopura, Rajshahi, Bangladesh

IST-0014