

Rinofen™

Flexofenadine Hydrochloride

Composition:

Rinofen™ 120 Tablet: Each film coated tablet contains Flexofenadine Hydrochloride USP 120 mg.

Rinofen™ 180 Tablet: Each film coated tablet contains Flexofenadine Hydrochloride USP 180 mg.

Description:

Rinofen™ (Flexofenadine) is an antihistamine with selective peripheral H₁-receptor antagonist activity. Flexofenadine 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. Excretion is mainly in the faeces, only 10% being present in the urine. Flexofenadine does not appear to cross the blood-brain barrier.

Indications:

Seasonal Allergic Rhinitis & Chronic Idiopathic Urticaria.

Dosage & 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 daily is recommended as the starting dose in pediatric patients with decreased renal function.

OR AS DIRECTED BY THE PHYSICIAN.

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.

Precautions:

Flexofenadine 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.

Use in Pregnancy & Lactation:

There are no adequate and well controlled studies in pregnant women. Flexofenadine should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. It is not known if Flexofenadine is excreted in human milk. Caution should be exercised when Flexofenadine is administered to a nursing woman.

Drug Interaction:

Plasma concentrations of Flexofenadine have been increased when given with Erythromycin or Ketoconazole. Antacid containing Aluminium and Magnesium Hydroxide reduces the absorption of Flexofenadine. Fruit juices including grapefruit may reduce the bioavailability of Flexofenadine and use together should be avoided.

Contraindications:

Flexofenadine is contraindicated in patients with known hypersensitivity to any of the ingredients.

Storage Condition:

Store in a cool & dry place, protect from light. Keep out of the reach of children.

Presentation:

Rinofen™ 120 Tablet: Each box contains 3x10's tablets in blister pack.

Rinofen™ 180 Tablet: Each box contains 3x10's tablets in blister pack.

Manufactured by:

Julphar Bangladesh Ltd.

Sreepur, Gazipur, Bangladesh.