

Fexo

COMPOSITION

Fexo® 60 : Each film coated tablet contains Fexofenadine Hydrochloride INN 60 mg.

Fexo® 120 : Each film coated tablet contains Fexofenadine Hydrochloride INN 120 mg.

Fexo® 180 : Each film coated tablet contains Fexofenadine Hydrochloride INN 180 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 is metabolised, 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 about 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.

INDICATIONS

Seasonal Allergic Rhinitis:

Fexo® tablets are indicated for the relief of symptoms associated with seasonal allergic rhinitis in adults and children 6 years of age and older.

Symptoms treated effectively were sneezing, rhinorrhea, itchy nose/palate/throat, itchy/watery/red eyes.

Chronic Idiopathic Urticaria:

Fexo® tablets are indicated for treatment of uncomplicated skin manifestations of chronic idiopathic urticaria in adults and children 6 years of age and older.

Fexofenadine Hydrochloride significantly reduces pruritus and the number of wheals.

DOSAGE AND ADMINISTRATION

Seasonal Allergic Rhinitis and Chronic Idiopathic Urticaria:

Adults and Children 12 years and older: The recommended dose of Fexo® is 60 mg twice 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.

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

DOSES IN RENAL IMPAIRMENT

This drug is known to be substantially excreted by the kidney and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection and it may be useful to monitor renal function.

Initial doses of Fexofenadine Hydrochloride in patients with renal impairment should be reduced to 60 mg once daily.

USE IN PREGNANCY AND 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.

It is not known if Fexofenadine is excreted in human milk. There are no adequate and well-controlled studies in women during lactation. Because many drugs are excreted in human milk, caution should be exercised when Fexofenadine is administered to a nursing woman.

DRUG INTERACTIONS

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

CONTRAINDICATIONS

Fexofenadine tablets are contraindicated in patients with known hypersensitivity to any of the ingredients.

PHARMACEUTICAL PRECAUTION

Store at a cool and dry place, protected from light and moisture. Keep out of reach of children.

HOW SUPPLIED

Fexo® 60 : Box containing 3 x10's tablets in blister pack.

Fexo® 120: Box containing 3 x10's tablets in blister pack.

Fexo® 180: Box containing 3 x10's tablets in blister pack.