Fexo®

Fexofenadine Hydrochloride USP

COMPOSITION

Fexo® 60 : Each film coated tablet contains Fexofenadine Hydrochloride USP 60 mg. **Fexo**® 120 : Each film coated tablet contains Fexofenadine Hydrochloride USP 120 mg. **Fexo**® 180 : Each film coated tablet contains Fexofenadine Hydrochloride USP 180 mg. **Fexo**® Suspension : Each 5 ml suspension contains Fexofenadine Hydrochloride USP 30 mg.

PHARMACOLOGY

Fexofenadine Hydrochloride is an antihistamine with selective peripheral H_1-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 metabolized, mostly by the intestinal mucosa, with only 0.5 to 1.5% of the dose undergoing hepatic biotransformation by the cyto-chrome P_{450} 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

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.

Fexo® Oral Suspension is indicated for the relief of symptoms associated with seasonal allergic rhinitis in children 2 to 11 years of age. Symptoms to treat effectively: 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. **Fexo**® Oral Suspension is indicated for treatment of uncomplicated skin manifestations of chronic idiopathic urticaria in children 6 months to 11 years of age. Fexofenadine Hydrochloride significantly reduces pruritus and the number of wheals.

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 whether Fexofenadine is excreted in human milk or not. Caution should be exercised when Fexofenadine is administered to a nursing woman.

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.

CONTRAINDICATION

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

DOSAGE AND ADMINISTRATION

Age group	Fexo® Tablet	Fexo® Oral Suspension	In case of decreased renal function
Adults & Children 12 years & older	60 mg twice daily or 120 mg once daily or 180 mg once daily with water	---	60 mg once daily is recommended as the starting dose
Children 6 to 11 years	30 mg twice daily or 60 mg once daily	30 mg (5 ml) twice daily	30 mg (5 ml) once daily is recommended as the starting dose
Children 2 to 5 years	----	30 mg (5 ml) twice daily	30 mg (5 ml) once daily is recommended as the starting dose
Children 6 months to less than 2 years	----	15 mg (2.5 ml) twice daily	15 mg (2.5 ml) once daily is recommended as the starting dose

In case of decreased renal function, care should be taken in dose selection and it may be useful to monitor renal function.

STORAGE CONDITION

Tablet: Store below 30°C, protect from light & moisture. **Suspension:** Store below 30°C. Protect from light.

Keep out of children's reach.

HOW SUPPLIED

Fexo® 60 : Each box contains 3 x 10 tablets in blister pack. **Fexo**® 120 : Each box contains 3 x 10 tablets in blister pack. **Fexo**® 180 : Each box contains 3 x 10 tablets in blister pack. **Fexo**® Susupension: Each bottle contains 50 ml suspension and measuring cup.

Manufactured by

SQUARE PHARMACEUTICALS LTD. BANGLADESH