Axodin®

Fexofenadine Hydrochloride
Tablet/Suspension

Description

Fexofenadine is a pharmacologically active metabolite of Terfenadine, is a non-sedating antihistamine with selective peripheral H_1 receptor antagonist activity.

Fexofenadine Hydrochloride is rapidly absorbed into the body following oral administration, with T_{max} occurring at approximately 1-3 hours post dose. The mean C_{max} value was approximately 427 ng/ml and 494 ng/ml following the administration of a 120 mg and 180 mg dose (once daily) respectively.

Fexofenadine is 60-70% plasma protein bound. Fexofenadine undergoes negligible metabolism, as it was the only major compound identified in urine and faeces of animal and man. The plasma concentration profiles of Fexofenadine follow a bi-exponential decline with a terminal elimination half-life ranging from 11 to 16 hours after multiple dosing. The single and multiple dose pharmacokinetics of Fexofenadine are linear between 40 mg and 240 mg taken daily. The major route of elimination is believed to be via biliary excretion while upto 10% of ingested dose is excreted unchanged through the urine.

Indications

Seasonal Allergic Rhinitis: Fexofenadine is indicated for the relief of symptoms associated with seasonal allergic rhinitis in adults and children 2 years of age and older.

Chronic Idiopathic Urticaria: Fexofenadine is indicated for treatment of uncomplicated skin manifestations of chronic idiopathic urticaria in adults and children 6 months of age and older.

Dosage and Administration

For Tablet

Seasonal Allergic Rhinitis and Chronic Idiopathic Urticaria: Adults and Children 12 Years and older: The recommended dose 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 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.

For oral Suspension

Seasonal Allergic Rhinitis: Children 2 to 11 Years: The recommended dose of oral suspension is 30 mg twice daily. A dose of 30 mg (5 ml) once daily is recommended as the starting dose in pediatric patients with decreased renal function. Shake bottle well, before each use.

Chronic Idiopathic Urticaria: Children 6 months to 11 years: The recommended dose of oral suspension is 30 mg (5 ml) twice daily for patients 2 to 11 years of age and 15 mg (2.5 ml) twice daily for patients 6 months to less than 2 years of age. For pediatric patients with decreased renal function, the recommended starting doses of oral suspension are 30 mg (5 ml) once daily for patients 2 to 11 years of age and 15 mg (2.5 ml) once daily for patients 6 months to less than 2 years of age. Shake bottle well, before each use.

Special Risk Groups

Studies in special risk groups (elderly, renally or hepatically impaired patients) indicate that it is not necessary to adjust the dose of Fexofenadine Hydrochloride in these patients.

Contraindications

The product is contraindicated in-patients with known hypersensitivity to any of its ingredients.

Interaction with other medicaments and other forms of interaction: Fexofenadine does not undergo hepatic bio-transformation and is therefore unlikely to interact with drugs that rely upon hepatic metabolis. Fexofenadine Hydrochloride at doses of 120 mg twice daily has been safely co-administered with erythromycin (500 mg three times daily) and ketoconazole (400 mg once daily) under steady state conditions in healthy volunteers. An increase in the level of Fexofenadine in plasma of 2 times was observed after co-administration of erythromycin or ketoconazole but this was not associated with any increase in adverse event or effects on the QT interval, compared to that seen when the drugs were given singly. Animal studies have shown that the increase in plasma level of Fexofenadine observed after co-administration of erythromycin or ketoconazole, appears to be due to an increase in gastrointestinal absorption and either a decrease in biliary clearance or gastrointestinal secretion respectively.

Adverse Reactions

In placebo-controlled trials, adverse events were comparable in Fexofenadine and placebo treated patients. Adverse events reported with *Fexofenadine include:*

Common: headache. *Uncommon:* fatigue, drowsiness, nausea, tachycardia, palpitations, dry mouth, nose and/or throat, dyspepsia and gastrointestinal disturbances (including diarrhea). *Rare:* taste disturbances, anaphylactic/ anaphylactic reactions, dyspnea, chest tightness, increased hair loss/hair thinning, photosensitivity, dysmenorrhea, menstrual disorders. As with other non-sedating antihistamines, dizziness, nervousness, agitation, sleep disorders, insomnia or paroniria may infrequently be reported by patients. The incidence of such reports under Fexofenadine was similar to the incidence under placebo.

Effects on ability to drive and use machine

On the basis of the pharmacodynamic profile and reported adverse events it is unlikely that Fexofenadine Hydrochloride tablets will produce an effect on the ability to drive or use machines. In objective tests, Fexofenadine Hydrochloride has been shown to have no significant effects on central nervous system function. This means that patients may drive or perform tasks that require concentration.

Fexofenadine did not cross the blood brain barrier in animal studies.

Overdose

Most reports of Fexofenadine Hydrochloride overdose contain limited information.

However, dizziness, drowsiness and dry mouth have been reported. Single doses upto 800 mg and doses upto 690 mg BID for 1 month or 240 mg QD for 1 year were studied in healthy subjects without the development of clinically significant adverse events as compared to placebo.

Use in Pregnancy and Lactation

No evidence of teratogenicity was observed in animal reproduction studies when Terfenadine was given throughout organogenesis. No effects on female fertility or on prenatal or postnatal development were observed in terfenadine animal studies at non-maternally toxic doses. Data from supporting pharmacokinetic studies showing the extent of exposure to Fexofenadine (an active metabolite of terfenadine) in the terfenadine animal studies demonstrate that they are relevant to the assessment of Fexofenadine Hydrochloride. However, the effects of fetal exposure at the higher doses of Fexofenadine tolerated in animals have not been examined. Fexofenadine should be used in pregnancy only if the potential benefit outweighs the potential risk to the fetus. There are no data on the content of human milk after administering Fexofenadine Hydrochloride. However, when Terfenadine was administered to nursing mothers Fexofenadine was found to cross into human breast milk. Therefore Fexofenadine is not recommended for mothers breast feeding their babies.

Pharmaceutical Precautions

Store in a cool & dry place, away from children.

Commercial Pack

Axodin® 60 Tablet: Box containing 50 tablets in 5 x 10's blister strips. Each tablet contains Fexofenadine Hydrochloride USP 60 mg.

Axodin® 120 Tablet: Box containing 30 tablets in 3 x 10's blister strips. Each tablet contains Fexofenadine Hydrochloride USP 120 mg.

Axodin® 180 Tablet: Box containing 30 tablets in 3 x 10's blister strips. Each tablet contains Fexofenadine Hydrochloride USP 180 mg.

Axodin® Suspension: Bottle containing 50 ml suspension. Each 5 ml contains Fexofenadine Hydrochloride USP 30 mg.

BEXIMCO PHARMA

Manufactured by

BEXIMCO PHARMACEUTICALS LTD.

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