For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory

Fexofenadine Hydrochloride Tablets

Fexine

Composition

Fexine 120

Each film-coated tablet contains

Fexofenadine Hydrochloride ..... 120 mg

Colours: Titanium Dioxide, Red Oxide of Iron & Yellow Oxide of Iron.

Fexine 180

Each film-coated tablet contains

Fexofenadine Hydrochloride ..... 180 mg

Colours: Titanium Dioxide & Yellow Oxide of Iron.

Description

Fexofenadine, an active metabolite of terfenadine, is a "non-sedating" antihistamine with selective peripheral H_1 receptor antagonist activity. Fexofenadine lacks the cardiotoxic potential of terfenadine since it does not block the potassium channel involved in repolarization of cardiac cells. Also, Fexofenadine does not possess appreciable anticholinergic, antidopaminergic or α-adrenergic blocking effects at usual antihistaminic doses.

Indications

Fexine is indicated for the relief of symptoms associated with allergic rhinitis and allergic skin conditions eg. chronic urticaria

Dosage and Administration

Allergic rhinitis

Adults and children aged 12 years and above

The recommended dose of Fexofenadine Hydrochloride for adults and children aged 12 years and over is 120 mg once daily.

Allergic skin conditions e.g. chronic urticaria

Adults and children aged 12 years and over

The recommended dose of Fexofenadine Hydrochloride for adults and children aged 12 years and over is 180 mg once daily.

Children aged < 12 years of age

The recommended dose of Fexofenadine Hydrochloride has not been studied in children under 12.

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.

Drug Interactions

Fexofenadine does not undergo hepatic biotransformation and is therefore unlikely to interact with drugs that rely upon hepatic metabolism. Plasma concentrations of Fexofenadine have been increased after the concomitant administration of erythromycin or ketoconazole, but unlike, terfenadine, is not associated with adverse effects on the QT interval. Fexofenadine Hydrochloride at doses of 120 mg twice daily has been safely coadministered with erythromycin (500 mg three times daily) and ketoconazole (400 mg once daily) under steady state conditions in healthy volunteers. Antacids containing aluminium and magnesium hydroxide have reduced the absorption of Fexofenadine.

Pregnancy and Lactation

There are no adequate and controlled studies to date using Fexofenadine in pregnant women. It should be used during pregnancy only when the potential benefits justify the possible risks to the fetus.

It is not known if Fexofenadine Hydrochloride is distributed into breast milk. It should therefore be used with caution in nursing women, and a decision should be made whether to discontinue nursing or the drug, taking into account the importance of the drug to the woman.

Effects on ability to drive and use machines

On the basis of the pharmacological 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. This means that patients may drive or perform tasks that require concentration.

Side-Effects

In placebo-controlled trials, which included 2461 patients receiving Fexofenadine Hydrochloride

at doses of 20 mg to 240 mg twice daily, adverse events were similar in Fexofenadine Hydrochloride and placebo-treated patients. The incidence of adverse events, including drowsiness, was not dose related and was similar across subgroups defined by age, gender, and race.

Common: headache

Uncommon: fatigue, drowsiness, nausea, tachycardia, dyspepsia, viral infection and dysmenorrhoea.

Overdosage

Single doses of Fexofenadine Hydrochloride up to 800 mg and doses up to 690 mg twice daily for one month were administered without the development of clinically significant adverse effects. In the event of overdose, consider standard measures to remove any unabsorbed drug from the GI tract. Symptomatic and supportive treatment is recommended.

Phamacological properties

Pharmacodynamic properties

Fexofenadine Hydrochloride is an antihistamine with selective peripheral H1-receptor antagonist activity. Fexofenadine inhibited histamine release from peritoneal mast cell in rats. In laboratory animals, no anticholinergic, alpha1-adrenergic or beta-adrenergic receptor blocking effects were observed. No sedative or other central nervous system effects were observed. The drug exhibits an antihistamine effect by 1 hour, achieves maximum effect at 2 to 3 hours, and the effect is still seen at 12 hours. There was no evidence of tolerance to these effects after 28 days of dosing.

Clinical studies have determined that Fexofenadine, even at high doses (ie, 240 milligrams twice daily), is safe in patients with seasonal allergic rhinitis. In these studies, there were no abnormalities in any electrocardiograph measurements, including QTc intervals, that were significantly different from placebo in patients with or without concomitant erythromycin or ketoconazole therapy.

No effect was observed on calcium channel current, delayed K^+ channel current, or action

potential duration in guinea pig myocytes, Na^+ current in rat neonatal myocytes, or on the delayed rectifier K^+ channel cloned from human heart at concentrations up to 1×10^{-5} M of Fexofenadine.

Pharmacokinetics

Fexofenadine is rapidly absorbed after oral administration with peak plasma concentrations being reached in 2 to 3 hours. Following single dose administrations of either the 120 and 180 mg tablet, mean maximum plasma concentrations were 427 and 494 ng/mL, respectively. Fexofenadine Hydrochloride pharmacokinetics are linear for oral doses up to a total daily dose of 240 mg (120 mg twice daily). Fexofenadine Hydrochloride is 60% to 70% bound to plasma proteins. About 5% of the total dose is metabolized, mostly by the intestinal mucosa, with only 0.5 to 1.5% of the dose undergoing hepatic biotransformation. Elimination half-lives of about 14 hours have been reported. Excretion is mainly in the faeces with only 10% being present in the urine. Fexofenadine does not appear to cross the blood-brain barrier.

Storage

Store below 25°C. Protect from moisture.

Presentation

Fexine-120	Blister Pack of 10 Tablets
Fexine-180	Blister Pack of 10 Tablets

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