Genfix® (FEXOFENADINE HCl)

60mg 120mg 180mg

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جین فِکس®
(فیکسوفینا ڈین ایچ سی ایل)

Fexofenadine Description
Fexofenadine hydrochloride is a histamine H1-receptor antagonist with the chemical name (±1)-4-[1-hydroxy-4-[4-(hydroxydiphenylmethyl)-1-piperidinyl]-butyl]-•, •-dimethyl benzeneacetic acid hydrochloride..
Composition
Genfix 60mg tablet: Each film coated tablet contain 60mg Fexofenadine Hydrochloride as an active ingredient.
Genfix 120mg tablet: Each film coated tablet contain 120mg Fexofenadine Hydrochloride as an active ingredient.
Genfix 180mg tablet: Each film coated tablet contain 180mg Fexofenadine Hydrochloride as an active ingredient.
Clinical Pharmacology
Mechanism of Action
Fexofenadine hydrochloride, the major active metabolite of terfenadine, is an with selective peripheral H1-receptor antagonist activity. Both enantiomers of fexofenadine hydrochloride displayed approximately equipotent antihistaminic effects. Fexofenadine hydrochloride inhibited antigen-induced bronchospasm in sensitized guinea pigs and histamine release from peritoneal mast cells in rats. The clinical significance of these findings is unknown. In laboratory animals, no anticholinergic or alpha1-adrenergic blocking effects were observed. Moreover, no sedative or other central nervous system effects were observed. Radiolabeled tissue distribution studies in rats indicated that fexofenadine does not cross the blood-brain barrier.
Pharmacokinetics
Absorption
Fexofenadine hydrochloride was rapidly absorbed following oral administration of a single dose of two 60mg tablets to healthy male volunteers with a mean time to maximum plasma concentration occurring at 2.6 hours post-dose. The tablet formulations are bioequivalent to the tablet when administered at equal doses. Fexofenadine hydrochloride pharmacokinetics are linear for oral doses up to a total daily dose of 240mg (120 mg twice daily). Co-administration of 180mg fexofenadine hydrochloride tablet with a high fat decreased the AUC and Cmax of fexofenadine by 21 and 20%, respectively.
Distribution
Fexofenadine hydrochloride is 60% to 70% bound to plasma , primarily albumin and •1-acid glycoprotein.
Metabolism
Approximately 5% of the total dose of fexofenadine hydrochloride was eliminated by hepatic metabolism.
Elimination
The mean elimination half-life of fexofenadine was 14.4 hours following administration of 60 mg twice daily in healthy volunteers.
Human mass balance studies documented a recovery of approximately 80% and 11% of the [14C] fexofenadine hydrochloride dose in the feces and urine, respectively. Because the absolute bioavailability of fexofenadine hydrochloride has not been established, it is unknown if the fecal component represents primarily unabsorbed drug or the result of biliary excretion.
Renally impaired
In subjects with mild to moderate (creatinine clearance 41 to 80 mL/min) and severe (creatinine clearance 11 to 40 mL/min) renal impairment, peak plasma levels of fexofenadine were 87% and 111% greater, respectively, and mean elimination half-lives were 59% and 72% longer, respectively, than observed in healthy volunteers. Peak plasma levels in subjects on dialysis (creatinine clearance - 10 mL/min) were 82% greater and half-life was 31% longer than observed in healthy volunteers. Based on increases in bioavailability and half-life, a dose of 60 mg once daily is recommended as the starting dose in patients with decreased renal function (see DOSAGE AND ADMINISTRATION).
Hepatically impaired
The pharmacokinetics of fexofenadine in subjects with hepatic disease did not differ substantially from that observed in healthy volunteers.
Indications and Usage
Seasonal Allergic Rhinitis
Fexofenadine hydrochloride 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
Fexofenadine hydrochloride tablets are indicated for treatment of uncomplicated skin manifestations of chronic idiopathic urticaria in adults and children 6 years of age and older. It significantly reduces pruritus and the number of wheals.
Contraindications
Fexofenadine hydrochloride tablets are contraindicated in patients with known hypersensitivity to any of its ingredients.
Precautions
Drug Interactions with Erythromycin and Ketoconazole
Fexofenadine has been shown to exhibit minimal (ca. 5%) metabolism. However, co-administration of fexofenadine hydrochloride with either ketoconazole or erythromycin led to increased plasma concentrations of fexofenadine. Fexofenadine had no effect on the pharmacokinetics of either erythromycin or ketoconazole.

Drug Interactions with Antacids
Administration of 120 mg of fexofenadine hydrochloride (2 x 60mg tablet) within 15 minutes of an aluminum and containing antacid decreased fexofenadine AUC by 41% and Cmax by 43%. Fexofenadine hydrochloride should not be taken closely in time with aluminum and magnesium containing antacids.
Pregnancy
Teratogenic Effects
Category C
There are no adequate and well controlled studies in pregnant women. Fexofenadine hydrochloride should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.
Nonteratogenic Effects
Dose-related decreases in pup weight gain and survival were observed in rats exposed to an oral dose of 150 mg/kg of terfenadine (approximately 3 times the maximum recommended human daily oral dose of fexofenadine hydrochloride of 180 mg based on comparison of fexofenadine hydrochloride AUCs).
Nursing Mothers
It is not known if fexofenadine is excreted in human milk. There are no adequate and well-controlled studies in women during lactation.
Pediatric Use
The recommended dose in patients 6 to 11 years of age is based on cross-study comparison of the pharmacokinetics of fexofenadine hydrochloride in adults and pediatric patients and on the safety profile of fexofenadine hydrochloride in both adult and pediatric patients at doses equal to or higher than the recommended doses.
Adverse Reactions
Adverse experience reported in placebo-controlled Allergic Rhinithis Clinical Trials at rates of greater than 1%. The incidence of adverse effect including viral infection (cold, flu), nausea dysmenorrhea, drowsiness dyspepsia fatigue.
Overdosage
Dizziness, drowsiness, and dry mouth have been reported. Single doses of fexofenadine hydrochloride up to 800mg (6 healthy volunteers at this dose level), and doses up to 690 mg twice daily for 1 month (3 healthy volunteers at this dose level) or 240 mg once daily for 1 year (234 normal volunteers at this dose level) were administered without the development of clinically significant adverse events as compared to placebo.
Dosage and Administration
Seasonal Allergic Rhinitis
Adults and Children 12 Years and Older
The recommended dose of fexofenadine hydrochloride tablets 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 (see CLINICAL PHARMACOLOGY).

Children 6 to 11 Years
The recommended dose of fexofenadine hydrochloride tablets 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 (see CLINICAL PHARMACOLOGY).

Chronic Idiopathic Urticaria

Adults and Children 12 Years and Older
The recommended dose of fexofenadine hydrochloride tablets is 60 mg twice daily with water. A dose of 60 mg once daily is recommended as the starting dose in patients with decreased renal function (see CLINICAL PHARMACOLOGY).

Children 6 to 11 Years
The recommended dose of fexofenadine hydrochloride tablets 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 (see CLINICAL PHARMACOLOGY).

Storage
Store in a cool dry place. Protect from heat & sunlight. Keep all medicines out of the reach of childern.

PRESENTATION
Genfix (Fexofenadine HCl) 60mg Tablets are available in Alu Alu Blister Pack of 10's tablets.
Genfix (Fexofenadine HCl) 120mg Tablets are available in Alu Alu Blister Pack of 10's tablets.
Genfix (Fexofenadine HCl) 180mg Tablets are available in Alu Alu Blister Pack of 10's tablets.

Please read the contents carefully before use.
This package insert is continually updated from time to time.

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔
خشک اور ٹھنڈی جگہ پر رکھیں اور دھوپ سے بچائیں۔
تمام دوائیں بچوں کی پہنچ سے دور رکھیں۔

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