100 X 180 MM

FEXOGLOB 120
Fexofenadine Hydrochloride Tablets USP 120 mg

Formulation
Each film coated tablet contains:
Fexofenadine Hydrochloride USP.....120 mg
Excipients.....Q.S
Colours: Titanium Dioxide BP

Indication
Fexofenadine hydrochloride 120 mg tablet is indicated in adults and children 12 years and older for the relief of symptoms associated with chronic idiopathic urticarial.

Pharmacodynamics
Pharmacotherapeutic group: Antihistamines for systemic use, ATC code: R06A X26.
Mechanism of action
Fexofenadine hydrochloride is a non-sedating H1 antihistamine. Fexofenadine is a pharmacologically active metabolite of terfenadine.
Clinical efficacy and safety
Human histamine wheal and flare studies following single and twice daily doses of fexofenadine hydrochloride demonstrate that the medicinal products exhibits an antihistaminic effect beginning within one hour, achieving maximum at 6 hours and lasting 24 hours. There is no evidence of tolerance to these effects after 28 days of dosing. A positive dose-response relationship between doses of 10 mg to 130 mg taken orally was found to exist. In this model of antihistaminic activity, it was found that doses of at least 130 mg were required to achieve a consistent effect that was maintained over a 24 hour period. Maximum inhibition in skin wheal and flare areas was greater than 80%. No significant differences in QTc, intervals were observed in seasonal allergic rhinitis patients given fexofenadine hydrochloride up to 240 mg twice daily for 2 weeks when compared to placebo. Also, no significant change in QTc intervals was observed in healthy subjects given fexofenadine hydrochloride up to 60 mg twice daily for 6 months. 400 mg twice daily for 6.5 days and 240 mg once daily for 1 year, when compared to placebo. Fexofenadine at concentrations 32 times greater than the therapeutic concentration in man had no effect on the delayed rectifier K+ channel cloned from human heart.
Fexofenadine hydrochloride (5-10 mg/kg per orally) inhibited antigen induced bronchospasm in sensitised guinea pigs and inhibited histamine release at supra- therapeutic concentrations (10- 100 µM) from peritoneal mast cells.

Pharmacokinetics
Absorption
Fexofenadine hydrochloride is rapidly absorbed into the body following oral administration, with Tmax occurring at approximately 1-3 hours post dose. The mean Cmax value was approximately 494 ng/ml following the administration of a 120 mg dose once daily.
Distribution
Fexofenadine is 60-70% plasma protein bound.
Biotransformation and elimination
Fexofenadine undergoes negligible metabolism (hepatic or non-hepatic), as it was the only major compound identified in urine and faeces of animals and man. The plasma concentration profiles of fexofenadine follow a bi-exponential decline with a terminal elimination half-life ranging from 11 to 15 hours after multiple dosing. The single and multiple dose pharmacokinetics of fexofenadine are linear for oral doses up to 120 mg BID. A dose of 240 mg BID produced slightly greater than proportional increase (8.8%) in steady state area under the curve, indicating that fexofenadine pharmacokinetics are practically linear at these doses between 40-mg and 240 mg taken daily. The major route of elimination is believed to be via biliary excretion while up to 10% of ingested dose is excreted unchanged through the urine.

Dosage and Administration
The recommended dose of fexofenadine hydrochloride for adults is 120 mg once daily taken before a meal.
Fexofenadine is a pharmacologically active metabolite of terfenadine.
Paediatric population
Adolescents aged 12 years and over
The recommended dose of fexofenadine hydrochloride for adolescents aged 12 years and over is 120 mg once daily taken before a meal.
Children under 12 years of age
The efficacy and safety of fexofenadine hydrochloride 120 mg has not been studied in children under 12.
Special populations
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.
Method of administration: Fexofenadine hydrochloride tablet is for oral use.

Warning and Precaution
As with most new medicinal products there is only limited data in the elderly and renally or hepatically impaired patients.
Fexofenadine hydrochloride should be administered with care in these special groups.
Patients with a history of or ongoing cardiovascular disease should be warned that, antihistamines as a medicine class, have been associated with the adverse reactions, tachycardia and palpitations.
Excipient
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free

Contraindications
Hypersensitivity to the active substance or to any of the excipients

Adverse Effects:
The following frequency rating has been used, when applicable:
Very common ≥1/10; Common ≥1/100 to <1/10; Uncommon ≥1/1,000 to <1/100; Rare ≥1/10,000 to <1/1,000;
Very rare <1/10,000; Not known (frequency cannot be estimated from the available data).
Within each frequency grouping, undesirable effects are presented in order of decreasing seriousness.
In adults, the following undesirable effects have been reported in clinical trials, with an incidence similar to that observed with placebo: Nervous system disorders, Common: headache, drowsiness, dizziness, Gastrointestinal disorders, Common: nausea, General disorders and administration site conditions, Uncommon: fatigue.
In adults, the following undesirable effects have been reported in post-marketing surveillance. The frequency with which they occur is not known (can not be estimated from available data):
Immune system disorders, Hypersensitivity reactions with manifestations such as angioedema, chest tightness, dyspnoea, flushing and systemic anaphylaxis, Psychiatric disorders, Insomnia, nervousness, sleep disorders or nightmares/excessive dreaming (paroniria), Cardiac disorders, Tachycardia, palpitations, Gastrointestinal disorders, Diarrhoea, Skin and subcutaneous tissue disorders, Rash, urticaria, pruritus

Pregnancy and Lactation:
Pregnancy
There are no adequate data from the use of fexofenadine hydrochloride in pregnant women.
Limited animal studies do not indicate direct or indirect harmful effects with respect to effects on pregnancy, embryonal/foetal development, parturition or postnatal development (see section 5.3). Fexofenadine hydrochloride should not be used during pregnancy unless clearly necessary.
Breast-feeding
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 hydrochloride is not recommended for mothers breast-feeding their babies.
Fertility
No human data on the effect of fexofenadine hydrochloride on fertility are available. In mice, there was no effect on fertility with fexofenadine hydrochloride treatment.

Overdose And Treatment:
Dizziness, drowsiness, fatigue and dry mouth have been reported with overdose of fexofenadine hydrochloride. Single doses up to 800 mg, and doses up to 690 mg twice daily for 1 month, or 240 mg once daily for 1 year have been administered to healthy subjects without the development of clinically significant adverse reactions as compared with placebo. The maximum tolerated dose of fexofenadine hydrochloride has not been established.
Standard measures should be considered to remove any unabsorbed medicinal product. Symptomatic and supportive treatment is recommended. Haemodialysis does not effectively remove fexofenadine hydrochloride from blood

Packaging:
10 tablets packed in one Alu-PVC blister and such 1 Alu-PVC blisters packed in one carton along with package insert.

Storage Condition:
Store below 25°C. Protect from light

Mfg. Lic. No. : G/25/1749
Manufactured in India by :
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