Fenix Tablets

فینکس گولیاں

(Fexofenadine Hydrochloride Tablets USP)

(فیکسوفیناڈین ہائیڈروکلورائیڈ)

COMPOSITION:
Each film coated tablet contains:
Fexofenadine Hydrochloride USP ... 60mg, 120mg or 180mg. [USP Specs.]

PHARMACOLOGY:
Mechanism of action: Fexofenadine Hydrochloride is a non-sedating H_1 antihistamine. Fexofenadine is a pharmacologically active metabolite of terfenadine.

PHARMACOKINETIC PROPERTIES
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 494ng/ml following the administration of a 180mg dose once daily.
Distribution:
Fexofenadine is 60-70% plasma protein bound.
Biotransformation and elimination:
Fexofenadine Hydrochloride undergoes negligible metabolism (hepatic or non-hepatic), as it was the only major compound identified in urine and faeces of animals and man. 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.

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

INDICATIONS:
Fenix Tablets are indicated in adults and children 12 years and older for the relief of symptoms associated with chronic idiopathic urticaria.

CONTRAINDICATIONS:
Hypersensitivity to the active substance or to any of the excipients.

DOSAGE AND ADMINISTRATION:
Adult Dose for Allergic Rhinitis and Urticaria:
180mg orally once a day OR 60mg orally 2 times a day. Maximum dose is 180mg/day. Tablets should be taken with water.
Pediatric Dose for Allergic Rhinitis and Urticaria:
6 months to 2 years: 15mg orally 2 times a day.
2 years to 11 years: 30mg orally 2 times a day.
12 years and older: 180mg orally once a day OR 60mg orally 2 times a day.

OVERDOSE:
Dizziness, drowsiness, fatigue and dry mouth have been reported with overdose of Fexofenadine Hydrochloride. Single doses up to 800mg and doses up to 690mg twice daily for 1 month or 240mg 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.

WARNINGS & PRECAUTIONS:
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.

Rev: 08-20/0 (706018)

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.

DRUG INTERACTIONS:
Fexofenadine Hydrochloride does not undergo hepatic biotransformation and therefore will not interact with other medicinal products through hepatic mechanisms. Coadministration of Fexofenadine Hydrochloride with erythromycin or ketoconazole has been found to result in a 2-3 times increase in the level of Fexofenadine Hydrochloride in plasma. The changes were not accompanied by any effects on the QT interval and were not associated with any increase in adverse reactions compared to the medicinal products given singly.
No interaction between Fexofenadine Hydrochloride and omeprazole was observed. However, the administration of an antacid containing aluminium and magnesium hydroxide gels 15 minutes prior to Fexofenadine Hydrochloride caused a reduction in bioavailability, most likely due to binding in the gastrointestinal tract. It is advisable to leave 2 hours between administration of Fexofenadine Hydrochloride and aluminium and magnesium hydroxide containing antacids.

PREGNANCY AND LACTATION:
Pregnancy: There are no adequate data from the use of Fexofenadine Hydrochloride in pregnant women. Fexofenadine Hydrochloride should not be used during pregnancy unless clearly necessary.
Breast-feeding: 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.

ADVERSE REACTIONS:
In adults, the following undesirable effects have been reported:

Nervous system disorders	Common: headache, drowsiness, dizziness
Gastrointestinal disorders	Common: nausea
General disorders and administration site conditions	Uncommon: fatigue
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	Diarrhea
Skin and subcutaneous tissue disorders	Rash, urticaria, pruritus

INSTRUCTIONS:
Store below 30°C. Protect from heat, light and moisture. Keep out of the reach of children.

PRESENTATION:
Fenix tablet 60mg is available in packs size of 10's.
Fenix tablet 120mg is available in pack size of 10's.
Fenix tablet 180mg is available in pack size of 10's.

ہدایات: ۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔
گرمی، روشنی اور نمی سے بچائیں۔ بچوں کی پہنچ سے دور رکھیں۔

Manufactured by:
NABIQASIM INDUSTRIES (PVT.) LTD.
17/24, Korangi Industrial Area,
Karachi-Pakistan.
PHARMA

Rev: 08-20/0 (706018)