# FEXOCARE
## (Fexofenadine as hydrochloride)

60mg
120mg
180mg
Tablets

**DRUG DESCRIPTION**

Fexofenadine, the active ingredient of **Fexocare** tablets, is a histamine H1-receptor antagonist with the chemical name) (±-4-[1nylmethyl)-1-Piperidinyl]-butyl]-a,a-dimethylhydroxy-4-beneneacetic acid hydrochloride.

**INDICATIONS**

**Fexocare** 60mg and 120mg tablets.

**Fexocare** 60mg or 120mg are indicated for the relief of symptoms associated with seasonal allergic rhinitis in adults and children 12 years of age and older. Symptoms treated effectively include sneezing, rhinorrhea, itchy nose/Palate/Throat, itchy/watery/red eyes.

**Fexocare 180mg tablets**

**Fexocare** 180mg tablet is indicated for treatment of uncomplicated skin manifestations of chronic idiopathic urticaria in adults and children.

**DOSAGE AND ADMINISTRATION**

Adults and Children 12 Years and Older:

**Fexocare** 60mg tablet twice daily with water.

**Fexocare** 120mg tablet once daily with water.

**Fexocare** 180mg tablet once daily with water.

A dose of 60mg once daily is recommended as a starting dose in patients with decreased renal function.

**Children 6 to 11 Years:**

A dose of 30mg once daily is recommended as a starting dose in pediatric patients with decreased renal function.

Fexofenadine should not be taken closely in time with aluminum and magnesium containing antacids.

In healthy adults patients, administration of 120mg of Fexofenadine (2x60mg) within 15 minutes of an aluminum and magnesium containing antacid decreased fexofenadine AUC By 41% and Cmax by 43%.

Fexofenadine has been shown to exhibit minimal metabolism. However co-administration of Fexofenadine with either ketcconazole or erythromycin led to increased plasma concentration of fexofenadine in healthy adult patients.

Fruit juices such as grape, orange and apple may reduce the bioavailability and exposure of fexofenadine. Therefore to maximize the effects of fexofenadine it is recommended that **Fexocare** tablets should be taken with water.

**CARCINOGENESIS, MUTAGENESIS, IMPAIRMENT OF FERTILITY**

No evidence of carcinogenicity was observed in an 19-month study in mice and in a 24-month study in rats at oral doses upto 150mg/kg of terfenadine (which led to fexofenadine exposures that were approximately 3 and 5 times the exposure at the maximum recommended daily oral dose of Fexofenadine in adults (180mg) and chilfen (60mg) respectively.

In rat fertility studies, Fexofenadine produced no effect on male or female fertility at average oral doses up to 4438mg/kg (which led to fexofenadine exposures that were approximately 13 times the exposure at the maximum recommended human daily oral dose of 180mg of Fexofenadine based on comparison of AUCs.)

**USE IN SPECIFIC POPULATIONS:**

**PREGNANCY**

Pregnancy categoryC. There was no evidence of teratogenicity in rats or rabbits at oral doses up to 300mg/kg. Nevertheless fexofenadine should be used during Pregnancy only if the potential benefit justifies the potential risk to the fetus.

**NURSING MOTHERS**

Because many drugs are excreted in human mlik, caution should be exercised when Fexofenadine in administered to a nursing woman.

**PEDIATRIC USE**

The recommended doses of Fexofenadine in padiatric patients 6 months to 11 Years of age are based on cross-study comparison of the pharmacokinetics of fexofenadine in adults and padiatric patients and on the safety profile of Fexofenadine in both adults and pediatric patients at doses equal to or higher than the recommended doses. The safety and effectiveness of Fexofenadine in pediatric patients under 6 months of age have not been established.

**GERIATRIC USE**

Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection and it may be useful to monitor renal function.

**RENAL IMPAIRMENT**

Based on increases in bioavailability and half life a dose of 60mg once daily is recommended as the starting dose in adult patients with decreased renal function (mild, moderate or severe renal

impairment)
The pharmacokinetics of Fexofenadine in patients with hepatic impairment did not differ substantially form that observed in healthy patients.

**OVERDOSE**

Dizziness drowsiness and dry mouth have been reported with Fexofenadine overdose. Single dose of Fexofenadine up to 800mg (6 healthy patients at this dose level) and doses up to 690mg twice daily for 1 month (3 healthy patients at this dose level) or 240mg once daily for 1 year (134 healthy patients at this dose level) were administered without the development of clinically significant adverse events as compared to placebo. No deaths occurred at oral doses of Fexofenadine to to 5000mg/kg in mice (110 times the maximum recommended daily oral dose in adults and children based on mg/m$^2$).

**MACHANISM OF ACTION**

Fexofenadine hydrochloride, the major active metabolite of terfenadine is and antihistamine with selective $H_1$-receptor antagonist activity. Both enantiomers of fexofenadine displayed approximately equipotent antihistaminic effects. In taboratory animals, No anticholinergic or alpha 1-adrenergic blocking effects were observed. Moreover, no sedative or other central nervous system effects were observed. Radio labeled tissue distribution studies in rats indicated that fexofenadine dose not cross the blood-brain barrier.

**DISTRIBUTION**

Fexofenadine is 60% to 70% bound to plasma proteins, primarily ablumin and α1-acid glycoprotein.

**ELIMINATION**

The mean elimination half-life of fexofenadine was 14.4 hours following administration of 60mg twice daily in healthy adult patients.
Human mass balance studies documented a recovery of approximately 80% and 11% of the {14C} Fexofenadine dose in the feces and urine, respectively. Because the absolute bio availability of fexofenadine has not been established, it is unknown if the fecal component represents primarily unabsorbed drug or is the result of biliary excretion.

**SPECIAL POPULATIONS**

**RENALLY IMPAIRED**

In patients with mild to moderate (creatinine clearance 41.80mL/min) and severe (creatinine clearance 11.40mL/min) renal impairment, peek plasma concentrations of fexofenadine were 87% and 111% greater, respectively and mean elimination half-lives were 59% and 72% longer respectively than observed in healthy patients. Peak plasma concentrations in patients on dialysis (creatinine clearance ≤ mL/min) were 82% greater and half-life 31% longer than observed in healthy patients. Based on increases in bioavailability and half-life a dose of 60mg once daily is recommended as the starting dose in adult patients with decreased renal function. For pediatric patients with decreased renal function, the recommended starting dose of fexofenadine is 30mg once daily for patients 2 to 11 years of age and 15mg once daily for patients 6 months to less than 2 years of age.

**HEPATICALLY IMPAIRED**

The pharmacokinetics of fexofenadine in patients with hepatic impairment did not differ substantially form the observed in healthy patients.

**AVAILABILITY:**

**Fexocare 60mg tablets:** Packet contains one blister of 10 tablets.
**Fexocare 120mg tablets:** Packet contains one blister of 10 tablets.
**Fexocare 180mg tablets:** Packet contains one blister of 10 tablets.

**DOSE:**

Use as prescribed by the physician.
Store at room temperature.
Protect form direct sun light, heat and moisture.
Keep away from children.

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

ہدایات: دوا کو کمرے کے درجہ حرارت پر رکھیں۔
روشنی، دھوپ اور نمی سے بچائیں۔ بچوں کی پہنچ سے دور رکھیں۔

صرف رجسٹرڈ ڈاکٹر کے نسخہ پر فروخت کریں۔

Manufactured by: