

Fexet™

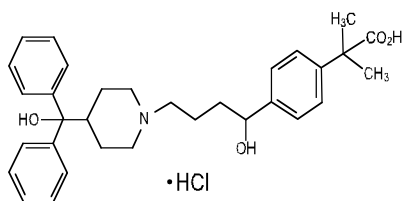
(Fexofenadine HCl Tablets USP)

Tablets

30mg, 60mg, 120mg, 180mg

DESCRIPTION

Fexofenadine hydrochloride, the active ingredient of FEXET, is a histamine H₁-receptor antagonist with the chemical name (±)-4-[1 hydroxy-4-[4-(hydroxydiphenylmethyl)-1-piperidiny]-butyl]-α,α-dimethyl benzeneacetic acid hydrochloride. The molecular formula is C₃₂H₃₉NO₄•HCl and has the following structural formula:



Fexofenadine hydrochloride

QUALITATIVE & QUANTITATIVE COMPOSITION
FEXET (Fexofenadine HCl) is available for oral administration as:

1. FEXET (Fexofenadine HCl) Tablets 30mg
Each film-coated tablet contains:
Fexofenadine HCl USP...30mg
2. FEXET (Fexofenadine HCl) Tablets 60mg
Each film-coated tablet contains:
Fexofenadine HCl USP...60mg
3. FEXET (Fexofenadine HCl) Tablets 120mg
Each film-coated tablet contains:
Fexofenadine HCl USP...120mg
4. FEXET (Fexofenadine HCl) Tablets 180mg
Each film-coated tablet contains:
Fexofenadine HCl USP...180mg

CLINICAL PHARMACOLOGY

Mechanism of Action

Fexofenadine hydrochloride is an active non-sedating antihistamine with selective peripheral H₁-receptor antagonist activity. It does not possess significant sedative or antimuscarinic action.

Pharmacokinetics

Absorption

Fexofenadine HCl is rapidly absorbed after oral administration with peak plasma concentrations being reached in 2 to 3 hours.

Distribution

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

Metabolism

Approximately 5% of the total oral dose is metabolized, mostly by intestinal mucosa, with only 0.5 to 1.5% of the dose undergoing hepatic biotransformation.

Excretion

Elimination half-life of about 14 hours has been reported although this may be prolonged in patients with renal impairment. Excretion is mainly in the faeces with only 10% being present in the urine.

Special Populations:

Geriatric Patients

In older subjects (>65 years old), peak levels of fexofenadine HCl were 99% greater than those observed in normal subjects (<65 years old). Mean elimination half-life was similar to those observed in normal subjects.

Renal Insufficiency

In patients with mild to moderate (creatinine clearance 41-80mL/min) and severe (creatinine clearance 11-40mL/min) renal impairment, peak plasma levels of fexofenadine HCl were 87% and 111% greater, respectively, and mean elimination half-lives were 59% and 72% longer, respectively, than observed in normal subjects.

THERAPEUTIC INDICATIONS

Seasonal Allergic Rhinitis

FEXET (Fexofenadine HCl) is indicated for the relief of symptoms associated with seasonal allergic rhinitis in adults and children 6 years of age and older.

Chronic Idiopathic Urticaria

FEXET (Fexofenadine HCl) is indicated for the treatment of uncomplicated skin manifestations of chronic idiopathic urticaria in adults and children 6 years of age and older. It significantly reduces pruritis and the number of wheals.

DOSAGE AND ADMINISTRATION

Seasonal Allergic Rhinitis

Adults and Children 12 Years and Older: The recommended dose of FEXET (Fexofenadine HCl) is 60mg twice daily, or 180mg once daily.

Children 6 to 11 Years: The recommended dose of FEXET (Fexofenadine HCl) is 30mg twice daily. A dose of 30mg once daily is recommended as the starting dose in pediatric patients with decreased renal function.

Chronic Idiopathic Urticaria

Adults and Children 12 Years and Older: The recommended dose of FEXET (Fexofenadine HCl) is 60mg twice daily. A dose of 60mg once daily is recommended as the starting dose in patients with decreased renal function.

Children 6 to 11 Years: The recommended dose of FEXET (Fexofenadine HCl) is 30mg twice daily. A dose of 30mg once daily is recommended as the starting dose in pediatric patients with decreased renal function.

Dosage in Renal Insufficiency:

Adults: In patients with decreased renal function the recommended dose of FEXET (Fexofenadine HCl) is 60mg once daily as the starting dose.

Pediatrics: In pediatric patients with decreased renal function the recommended dose of FEXET (Fexofenadine HCl) is 30mg once daily as the starting dose.

ADVERSE EFFECTS

Fexofenadine HCl is generally well tolerated. However following are few of the side effects that are known to be associated with the use of fexofenadine HCl.

Headache, drowsiness, nausea, vomiting, fatigue and dizziness.

CONTRAINDICATIONS

Fexofenadine HCl is contraindicated in patients with known hypersensitivity to the drug or any component of the product.

PRECAUTIONS*Pregnancy*

Fexofenadine HCl 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 milk, caution should be exercised when fexofenadine HCl is administered to a nursing woman.

Pediatric Use

The safety and effectiveness of fexofenadine HCl in pediatric patients under 6 years of age have not been established.

Geriatric Use

This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. 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.

Drug Interactions*Antacids*

Antacids containing aluminium and magnesium hydroxide have reduced the absorption of fexofenadine HCl.

STORAGE

Store below 30°C

Protect from sunlight & moisture.

The expiration date refers to the product correctly stored at the required conditions.

HOW SUPPLIED

1. Fexet (Fexofenadine HCl) Tablets 30mg are available in blister packs of 10 tablets.
2. Fexet (Fexofenadine HCl) Tablets 60mg are available in blister packs of 10 tablets.
3. Fexet (Fexofenadine HCl) Tablets 120mg are available in blister packs of 10's and 20's and in bottle's of 100 tablets.
4. Fexet (Fexofenadine HCl) Tablets 180mg are available in blister packs of 10's and 20's.

Keep out of reach of children.

To be sold on prescription of a registered medical practitioner only.

Please read the contents carefully before use.

This package insert is continually updated from time to time.



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A member of

The Getz Group,

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Manufactured by: Getz Pharma (Pvt.) Limited, 29-30/27, K.I.A., Karachi-74900, Pakistan.

EX05-200006672