SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF DRUG PRODUCT

Fexet Tablet 180mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains:
Fexofenadine HCl….180mg

3. PHARMACEUTICAL FORM

White oblong shaped film-coated tablet, engraved 'GETZ' on one side and bisect line on other side.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Seasonal Allergic Rhinitis
FEXET (Fexofenadine) 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) is 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.

4.2 Posology and method of administration

Seasonal Allergic Rhinitis
Adults and Children 12 Years and Older: The recommended dose of FEXET (Fexofenadine) is 60mg twice daily, or 180mg once daily.
Children 6 to 11 Years: The recommended dose of FEXET (Fexofenadine) 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) is 60mg twice daily. A dose of 60mg once daily is recommended as the starting dose in patient with decreased renal function
Children 6 to 11 Years: The recommended dose of FEXET (Fexofenadine) 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) is 60mg once daily as the starting dose.
Pediatrics: In pediatric patients with decreased renal function the recommended dose of FEXET (Fexofenadine) is 30mg once daily as the starting dose.

4.3 Contraindications

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

4.4 Special warnings and special precautions for use

Geriatric Use: This drug is known to be substantially excreted by 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.

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

4.5 Interaction with other medicaments

Antacids: Antacids containing aluminum and magnesium hydroxide have reduced the absorption of Fexofenadine HCl.

4.6 Pregnancy and Lactation

Pregnancy: Fexofenadine HCl should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Lactation: Because many of drugs are excreted in human milk, cautions should be exercised when fexofenadine HCl is administered in Nursing mothers.

4.7 Effects on ability to drive and use machine

Based on the pharmacodynamics profile and reported adverse events it is unlikely that fexofenadine hydrochloride will affect the ability to drive or use machines. In objective tests fexofenadine has been shown to have no significant effects on the central nervous system function. This means that patients may drive or perform tasks that require concentration. However, in order to identify particularly sensitive people who, have an unusual reaction to the medicine, it is advisable to check the patient's response to the medicine before driving or performing complicated tasks

4.8 Undesirable effects

Fexofenadine 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, dizziness.

4.9 Overdose

Dizziness, drowsiness, fatigue and dry mouth have been reported with overdose of fexofenadine HCl. Standard measures should be considered to remove any unabsorbed medicinal product. Symptomatic and supportive treatment is recommended. Hemodialysis does not effectively remove fexofenadine HCl from blood.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamics properties

Pharmacotherapeutic group: Antihistamines for systemic use.
ATC code: R06A X26

Mechanism of Action

Fexofenadine is a non-sedating H_1 antihistamine. Fexofenadine is a pharmacologically active metabolite of terfenadine.

Histamine provocation tests in humans, in which fexofenadine was administered once and twice daily, demonstrate that the drug exhibits an antihistamine effect beginning within 1 hour, reaching maximum at 6 hours and lasting at least 24 hours. There was no evidence of tolerance after 28 days of treatment. There was a positive dose response relationship with oral doses of 10 mg-130 mg. In this model of antihistamine activity, it was found that doses of at least 130 mg were required to achieve a constant effect over a 24-hour period. Maximum inhibition in the provoked skin area exceeded 80%. Clinical studies for treatment of seasonal allergic rhinitis have shown that a dose of 120 mg is sufficient for 24-hour efficacy.

Clinical Pharmacology

Mechanism of action

Fexofenadine hydrochloride is an active non-sedating antihistamine with selective peripheral H_1-receptor antagonist activity. It does not possess significant sedative or ant muscarinic actions.

5.2 Pharmacokinetic properties

Absorption

Fexofenadine 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 1-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 plasma levels of fexofen-adine were 99% greater than those observed in normal subjects (<65 years old). Mean elimination half-lives 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 were 87% and 111% greater, respectively, and mean elimination half-lives were 59% and 72% longer, respectively, than observed in normal subjects.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients
- Lactose Monohydrate
- Microcrystalline Cellulose (Avicel PH-102)
- Pregelatinized Starch
- Croscarmellose Sodium
- Magnesium Stearate
- Hypromellose 5CPS (Methocel E-5)
- Titanium Dioxide
- Macrogols (P.E.G 6000)
- Purified Talc
- Purified Water

6.2 Incompatibilities
None

6.3 Shelf-life
3 Years

6.4 Special precautions for storage
- Store below 30°C.
- Protect from sunlight and moisture
- Keep out of reach of children

6.5 Nature and contents of container
Fexet (Fexofenadine HCl) Tablet 180mg are available in Alu-Alu blister Pack of 2x10's along with a package insert in a unit carton.

6.6 Instructions for use/handling
To be dispensed on medical prescription only
Keep all medicines out of the reach of children.

7. MARKETING AUTHORISATION HOLDER
Getz Pharma (Private) Limited
29-30/27, Korangi Industrial Area Karachi 74900, Pakistan
Tel: (92-21) 111-111-511
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8. PRODUCT REGISTRATION NUMBER

007211-EX

9. DATE OF PRODUCT REGISTRATION ISSUED

June 29, 2018