Summary of Product Characteristics for Pharmaceutical Products

1. NAME OF DRUG PRODUCT

Fexet (Fexofenadine Hydrochloride) Tablets 120mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains:
Fexofenadine HCI BP...120mg

Excipients with known effect:
Lactose Monohydrate

For the full list of excipients, see section 6.1.

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

Fexet (Fexofenadine HCI) is indicated in adults and children 12 years and older for the relief of symptoms associated with seasonal allergic rhinitis.

4.2 Posology and Method of Administration

Adults
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

- **Children aged 12 years and over**
  The recommended dose of fexofenadine hydrochloride for children aged 12 years and over is 120 mg one 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.

- **In children from 6 to 11 years of age**

Fexofenadine hydrochloride 30 mg tablet is the appropriate formulation for administration and dosing in this population.

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.

4.3 Contraindications:

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

4.4 Special warnings and special precautions for use

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.

As with most new medicinal products there is only limited data in the older people and renally or hepatically impaired patients. Fexofenadine hydrochloride should be administered with care in these special groups.

Sodium
Each tablet contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

4.5 Interaction with other medicaments

Fexofenadine does not undergo hepatic biotransformation and therefore will not interact with other medicinal products through hepatic mechanisms.

Fexofenadine is a P-glycoprotein (P-gp) transporter and organic-anion-transporting polypeptide (OATP) substrate. Concomitant use of fexofenadine with P-gp inhibitors or inducers can affect the exposure to fexofenadine. Co-administration of fexofenadine hydrochloride with P-gp inhibitors erythromycin or ketoconazole has been found to result in 2-3 times increase in the level of fexofenadine 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.

A clinical drug-drug interaction study showed that co-administration of apalutamide (a weak inducer of P-gp) and a single oral dose of 30 mg fexofenadine resulted in a 30% decrease in AUC of fexofenadine.

No interaction between fexofenadine 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.

4.6 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. 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.

4.7 Effects on ability to drive and use machine

On the basis of the pharmacodynamic profile and reported adverse reactions it is unlikely that fexofenadine hydrochloride tablets will produce an effect on the ability to drive or use machines. In objective tests, Fexofenadine hydrochloride has been shown to have no significant effects on central nervous system function. This means that patients may drive or perform tasks that require concentration. However, in order to identify sensitive people who have an unusual reaction to medicinal products, it is advisable to check the individual response before driving or performing complicated tasks.

4.8 Undesirable effects

Nervous system disorders
Common:
Headache
Drowsiness
Dizziness

Gastrointestinal disorders
Common:
Nausea

General disorders and administration site conditions
Uncommon:
Fatigue

'Reporting of suspected adverse reactions: Healthcare professionals are requested to report any Suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org'

4.9 Overdose

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.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic Group: Antihistamines for Systemic Use
ATC Code: R06AX26

Mechanism of Action:
Fexofenadine hydrochloride is a non-sedating H_1 antihistamine. Fexofenadine is a pharmacologically active metabolite terfenadine.

5.2 Pharmacokinetic Properties

Absorption:
Fexofenadine hydrochloride is rapidly absorbed into the body following oral administration, with T_{max} occurring at approximately 1-3 hours post dose. The mean C_{max} value was approximately 427 ng/ml following the administration of a120 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.

5.3 Preclinical safety data

Dogs tolerated 450 mg/kg administered twice daily for 6 months and showed no toxicity other than occasional emesis. Also in single dose dog and rodent studies, no treatment-related gross findings were observed following necropsy.
Radio labelled fexofenadine hydrochloride in tissue distribution studies of the rat indicated that fexofenadine did not cross the blood brain barrier.
Fexofenadine hydrochloride was found to be non-mutagenic in various *in vitro* and *in vivo* mutagenicity tests.
The carcinogenic potential of fexofenadine hydrochloride was assessed using terfenadine studies with supporting pharmacokinetic studies showing fexofenadine hydrochloride exposure (via plasma AUC values). No evidence of carcinogenicity was observed in rats and mice given terfenadine (up to 150 mg/kg/day).
In a reproductive toxicity study in mice, fexofenadine hydrochloride did not impair fertility, was not teratogenic and did notimpair pre- or postnatal development.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

- Lactose Monohydrate
- Microcrystalline Cellulose (Avicel PH-102)
- Pregelatinized Starch
- Croscarmellose Sodium
- Magnesium Stearate
- Methocel E-5 (HPMC 5CPS)
- Titanium Dioxide
- Macrogol (P.E.G 6000)

6.2 Incompatibilities

Not applicable

6.3 Shelf-life

3 Years

6.4 Special precautions for storage

- Store below 30°C.
- Protect from sunlight & moisture.
- The expiration dates refer to the product correctly stored in the required conditions.

6.5 Nature and contents of container

Fexet (Fexofenadine Hydrochloride) Tablets 120mg are available in Alu-Alu blister pack of 20's (2 x 10's) tablets.

6.6 Special precautions for disposal

No special requirements.

6.7 Instructions for use/handling

- Keep out of reach of children.
- To be sold on prescription of a registered medical practitioner only.

7. MARKETING AUTHORISATION HOLDER

Getz Pharma (Private) Limited
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8. MARKETING AUTHORIZATION NUMBER

H2004/215/15640/R1

9. DATE OF FIRST AUTHORIZATION / RENEWAL OF THE AUTHORIZATION

July 28, 2004

10. DATE OF REVISION OF THE TEXT

February 03, 2026