Sterling Lab

Summary of Product Characteristics

ALLEFAST -120

(Fexofenadine Hydrochloride Tablets USP 120 mg)

1. NAME OF THE MEDICINAL PRODUCT

ALLEFAST -120 (Fexofenadine Hydrochloride Tablets USP 120 mg)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

The active ingredient is Fexofenadine Hydrochloride USP 120 mg

3. PHARMACEUTICAL FORM

Pharmaceutical form: Tablets.

Description: White coloured, circular biconvex, film coated tablets with plain on both sides.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Seasonal Allergic Rhinitis- Allefast is indicated for the relief of symptoms associated with seasonal allergic rhinitis in adults and children 6 years of age and older. Symptoms treated effectively were sneezing, rhinorrhea, itchy nose/palate/throat, itchy/watery/red eyes.

Chronic Idiopathic Urticaria- Allefast 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 Allefast is 120 mg once daily as a single or in a divided dose. A dose of 60 mg once daily is recommended as the starting dose in patients with decreased renal function.

Children 6 to 11 years: The recommended dose of Allefast is 30 mg twice daily. A dose of 30 mg 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 Allefast is 180 mg as a single or in two divided doses. A dose of 60 mg once daily is recommended as the starting dose in patients with decreased renal function.

Children 6 to 11 years: The recommended dose of Allefast is 30 mg twice daily. A dose of 30 mg once daily is recommended as the starting dose in pediatric patients with decreased renal function.

4.3 Contraindications

Fexofenadine Hydrochloride is contraindicated in patients with known hypersensitivity to any of its ingredients.

4.4 Special warnings and precautions for use

Fexofenadine lacks sedative effects. Patients should, however, be warned that a small number of individuals may experience sedation. It is therefore advisable to determine individual response before driving or performing complicated tasks. This effect may be compounded by simultaneous intake of alcohol or other central nervous system depressants.

4.5 Interaction with other medicinal products and other forms of interaction

Substrate of CYP3A4 (minor); Inhibits CYP2D6 (weak).

Antacids (containing aluminum or magnesium):

AUC of fexofenadine was decreased by 41% and C_{max} by 43% with concomitant administration; separate administration is recommended.

Erythromycin: Levels of fexofenadine are increased (82% higher); not associated with increased adverse effects and no difference in QTc intervals.

Ketoconazole: Levels of fexofenadine are increased (135% higher); not associated with increased adverse effects and no difference in QTc intervals.

Ethanol: Avoid ethanol (although limited with fexofenadine, may increase risk of sedation).

4.6 Fertility, pregnancy and lactation

Pregnancy: There are no adequate and well controlled studies in pregnant women.

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

Nursing Mothers: There are no adequate and well controlled studies in women during lactation.

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

Pediatric Use: this drug product in not labeled for use in children less than 6 years of age.

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 may be useful to monitor renal function.

Fexofenadine lacks sedative effects. Patients should, however, be warned that a small number of individuals may experience sedation. It is therefore advisable to determine individual response before driving or performing complicated tasks. This effect may be compounded by simultaneous intake of alcohol or other central nervous system

depressants.

4.7 Effects on ability to drive and use machines

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

The following frequency rating has been used, when applicable:
Very common ≥1/10;
Common ≥1/100 and <1/10;
Uncommon ≥1/1,000 and <1/100;
Rare ≥1/10,000 and <1/1,000;
Very rare <1/10,000 and not known (frequency cannot be estimated from the available data).

Within each frequency grouping, undesirable effects are presented in order of decreasing seriousness.

In adults, the following undesirable effects have been reported in clinical trials, with an incidence similar to that observed with placebo:

Nervous system disorders
Common: headache, drowsiness, dizziness
Gastrointestinal disorders
Common: nausea
General disorders and administration site conditions
Uncommon: fatigue
In adults, the following undesirable effects have been reported in post-marketing surveillance. The frequency with which they occur is not known (cannot be estimated from available data):
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
diarrhoea
Skin and subcutaneous tissue disorders
rash, urticaria, pruritus
Reporting of suspected adverse reactions

4.9 Overdose

Most reports of fexofenadine hydrochloride overdose have been infrequent and contain limited information. However, frequently reported symptoms are dizziness, drowsiness and dry mouth. In the event of overdose, standard measures to remove any unabsorbed drug should be considered. Symptomatic and supportive treatment is recommended. Hemodialysis did not effectively remove fexofenadine from blood (up to 1.7 % removed) following terfenadine administration.

5.0 Pharmacological properties

5.1 Pharmacodynamic properties

Mechanism of Action- Fexofenadine Hydrochloride is a second-generation, long lasting H1-receptor antagonist (antihistamine) which has a selective and peripheral H1-antagonist action.

Fexofenadine competes with free histamine for binding at H1-receptors in the GI tract, large blood vessels, and bronchial smooth muscle. This block the action of endogenous histamine, which subsequently leads to temporary relief of the negative symptoms brought on by histamine.

Fexofenadine exhibits no anticholinergic, alpha1- adrenergic or beta-adrenergic-receptor blocking effects. Fexofenadine, like other second and third generation antihistamines, does not readily cross the blood-brain barrier and so causes less drowsiness than first-generation histamine receptor antagonists. Fexofenadine lacks the cardiotoxic potential, since it does not block the potassium channel involved in repolarization of cardiac cells.

5.2 Pharmacokinetic properties

Onset of action	- 60 minutes.
Duration	- Antihistaminic effect: 12 hours.
Protein binding	- 60% to 70%, primarily albumin and alpha1-acid glycoprotein.
Metabolism	- ~5% mostly by gut flora; 0.5% to 1.5% by CYP.
Half-life elimination	- 14.4 hours.
Time to peak, serum	- ~2.6 hours.
Excretion	- Feces (~80%) and urine (~11%) as unchanged drug.

5.3 Preclinical safety data

There is no preclinical safety data available.

6.0 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose BP
Starch BP
Microcrystalline Powder BP
Croscarmellose Sodium BP
Povidone BP
Purified water BP
Collidal silicon Dioxide BP
Sodium Starch Glycolate BP
Sodium Lauryl Sulphate BP
Magnesium Stearate BP
Pharmacoat 606
Propylene Glycol BP
Titanium Dioxide BP
Isopropyl Alcohol BP
Methylene Chloride BP

6.2 Incompatibilities

Not applicable

6.3 Shelf life

36 months from the date of manufacture.

6.4 Special precautions for storage

Store at a temperature not exceeding 30^{O}C. Protect from light.

6.5 Nature and contents of container

Blister pack of 10 X 10 Tablets in a carton box

6.6 Special precautions for disposal <and other handling>

Not applicable.

7. MARKETING AUTHORISATION HOLDER

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8. MARKETING AUTHORISATION NUMBER(S)

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9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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10. DATE OF REVISION OF THE TEXT

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