4.75”

7.15”

Fexsel Tablet/Suspension

(Fexofenadine HCl)

فیکسل گولیاں / سسپنشن

(فیکسوفیناڈین ایچ سی ایل)

COMPOSITION:

FEXSEL Tablet 60mg
Each film coated tablet contains:
Fexofenadine HCl 60mg
(BP Specifications)
FEXSEL Tablet 120mg
Each film coated tablet contains:
Fexofenadine HCl 120mg
(BP Specifications)
FEXSEL Tablet 180mg
Each film coated tablet contains:
Fexofenadine HCl 180mg
(BP Specifications)
FEXSEL Suspension 30mg/5ml
Each 5ml contains:
Fexofenadine HCl 30mg
(Innovator's Specifications)

DESCRIPTION:

Fexofenadine hydrochloride is an antihistamine drug used in the treatment of hay fever and similar allergy symptoms. Fexofenadine, like other second and third-generation antihistamines, does not readily pass through the blood-brain barrier, and so causes less drowsiness than first-generation histamine-receptor antagonists.

MODE OF ACTION:

Like other H1-blockers, Fexofenadine competes with free histamine for binding at H1-receptors in the GI tract, large blood vessels, and bronchial smooth muscle. This blocks the action of endogenous histamine, which subsequently leads to temporary relief of the negative symptoms (e.g. nasal congestion, watery eyes) brought on by histamine. Fexofenadine exhibits no anticholinergic, anti-dopaminergic, alpha1-adrenergic or beta-adrenergic-receptor blocking effects.

INDICATIONS:

Seasonal Allergic Rhinitis
FEXSEL tablets are indicated for the relief of symptoms associated with seasonal allergic rhinitis in adults and children 6 years of age and older.
FEXSEL Oral Suspension is indicated for the relief of symptoms associated with seasonal allergic rhinitis in children 2 to 11 years of age.
Symptoms treated effectively were sneezing, rhinorrhea, itchy nose/palate/throat, itchy/watery/red eyes.
Chronic Idiopathic Urticaria
FEXSEL tablets are indicated for treatment of uncomplicated skin manifestations of chronic idiopathic urticaria in adults and children 6 years of age and older.
FEXSEL Oral Suspension is indicated for treatment of uncomplicated skin manifestations of chronic idiopathic urticaria in children 6 months to 11 years of age.
Fexofenadine hydrochloride significantly reduces pruritus and the number of wheals.

DOSAGE & ADMINISTRATION

• FEXSEL Tablet
Seasonal Allergic Rhinitis and Chronic Idiopathic Urticaria
Adults and Children 12 Years and Older:
The recommended dose of FEXSEL is 60 mg twice daily or 180 mg once daily with water. 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 FEXSEL is 30 mg twice daily with water. A dose of 30 mg once daily is recommended as the starting dose in pediatric patients with decreased renal function.
• FEXSEL Oral Suspension
Seasonal Allergic Rhinitis
Children 2 to 11 Years:
The recommended dose of FEXSEL Oral Suspension is 30 mg twice daily. A dose of 30 mg (5 mL) once daily is recommended as the starting dose in pediatric patients with decreased renal function.
Chronic Idiopathic Urticaria
Children 6 Months to 11 Years:
The recommended dose of FEXSEL Oral Suspension is 30 mg (5 mL) twice daily for patients 2 to 11 years of age and 15 mg (2.5 mL) twice daily for patients 6 months to less than 2 years of age. For pediatric patients with decreased renal function, the recommended starting doses of FEXSEL Oral Suspension are 30 mg (5 mL) once daily for patients 2 to 11 years of age and 15 mg (2.5 mL), once daily for patients 6 months to less than 2 years of age.

PRECAUTIONS:

As with most new medicinal products there is only limited data in the elderly and renally or hepatically impaired patients. Fexofenadine hydrochloride should be administered with care in these special groups.
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.
Pregnancy
Fexofenadine hydrochloride should not be used during pregnancy unless clearly necessary.
Breastfeeding
Fexofenadine hydrochloride is not recommended for mothers breastfeeding their babies.

PHARMACOKINETICS:

Absorption:
After oral application, maximum plasma concentrations are reached after two to three hours. Fexofenadine should not be taken with a high fat meal, as mean concentrations of fexofenadine in the bloodstream are seen to be reduced from 20-60% depending on form of medication (tablet, ODT, or suspension).
Distribution:
Fexofenadine is 60-70% bound to plasma proteins, mostly albumin.
Metabolism:
Fexofenadine is a substrate of CYP3A4. However, only about 5% is metabolized by the liver, indicating that the role of hepatic metabolism is relatively minor in its clearance from the body.
Elimination:
Most of the substance is eliminated unchanged via the feces (80%) and urine (11–12%).

SIDE EFFECTS:

The most common side effect demonstrated in adults was headache, but some also experienced back and muscle pain, miosis or pinpoint pupils, nausea, drowsiness, and menstrual cramps. There have also been rare reports of anxiety and insomnia. The most common side effects demonstrated during clinical trials were cough, upper respiratory tract infection, fever, and otitis media for children ages 6 to 11 and fatigue for children ages 6 months to 5 years.

DRUG INTERACTIONS:

Fexofenadine does not undergo hepatic biotransformation and therefore will not interact with other medicinal products through hepatic mechanisms. Co administration of fexofenadine hydrochloride with erythromycin or ketoconazole has been found to result in a 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.
Animal studies have shown that the increase in plasma levels of fexofenadine observed after co administration of erythromycin or ketoconazole, appears to be due to an increase in gastrointestinal absorption and either a decrease in biliary excretion or gastrointestinal secretion, respectively.
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.

CONTRAINDICATIONS:

Fexofenadine hydrochloride is contraindicated in patients with known hypersensitivity to Fexofenadine and any of the ingredient. Rare Cases of hypersensitivity reactions with manifestations such as angioedema, chest tightness, dyspnea, flushing and systemic anaphylaxis have been reported.

STORAGE & INSTRUCTIONS:

Store between 15-25°C. Protect from heat, sunlight and moisture. Do not freeze. Keep away from the reach of children.
(To be sold on the prescription of a registered medical practitioner only.)

HOW SUPPLIED:

FEXSEL Tablet 60mg
10 Tablets.
FEXSEL Tablet 120mg
10 Tablets.
FEXSEL Tablet 180mg
10 Tablets.
FEXSEL Suspension 30mg/5ml
60ml

خوراک وطریقہ استعمال:

ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

ہدایات:

دوا کو ۱۵-۲۵ ڈگری سینٹی گریڈ درجہ حرارت کے درمیان رکھیں۔
دھوپ، گرمی اور نمی سے بچائیں۔ بچوں کی پہنچ سے دور رکھیں۔
صرف رجسٹرڈ ڈاکٹر کے نسخہ کے مطابق فروخت کریں۔

Manufactured by:
PHARMASOL PRIVATE LIMITED
Plot # 549,Sundar Industrial Estate,
Lahore, Pakistan.