

#### Fexofenadine Hydrochloride USP

#### COMPOSITION

Fexten 120 Tablet: Each film coated tablet contains Fexofenadine

Hydrochloride USP 120 mg.

**Fexten Suspension:** Each 5 ml suspension contains Fexofenadine Hydrochloride USP 30 mg.

#### **PHARMACOLOGY**

Fexten (Fexofenadine Hydrochloride) is an antihistamine with selective peripheral H<sub>1</sub>-receptor antagonist activity. It is rapidly absorbed after oral administration and peak plasma concentration is reached in 2-3 hours. It does not appear to cross the blood brain barrier.

#### **INDICATIONS**

It is indicated for the relief of symptoms associated with seasonal allergic rhinitis in adults and children. It is also indicated for the treatment of uncomplicated skin manifestations of chronic idiopathic urticaria.

#### **DOSAGE AND ADMINISTRATION**

Disease	Age group	Fexten Tablet	Fexten Suspension	In case of impaired renal function
Seasonal Allergic Rhinitis	Adults and children 12 years and older	60 mg twice daily or 120 mg once daily or 180 mg once daily		60 mg once daily
	Children from 6 to 11 years	30 mg twice daily or 60 mg once daily		30 mg once daily
	Children from 2 to 11 years		30 mg or 5 ml (1tsp) twice daily	30 mg or 5 ml (1tsp) once daily
Chronic Idiopathic Urticaria	Adults and children 12 years and older	60 mg twice daily or 120 mg once daily or 180 mg once daily		60 mg once daily
	Children from 6 to 11 years	30 mg twice daily or 60 mg once daily		30 mg once daily
	Children from 6 months to less than 2 years		15 mg or 2.5 ml (½ tsp) twice daily	15 mg or 2.5 ml (½ tsp) once daily
	Children from 2 to 11 years		30 mg or 5 ml (1tsp) twice daily	30 mg or 5 ml (1tsp) once daily

# CONTRAINDICATIONS

Contraindicated in patients with known hypersensitivity to Fexofenadine Hydrochloride or any of its ingredients.

# WARNING AND PRECAUTION

Caution should be exercised in elderly patient and patient with decreased renal function.

# SIDE EFFECTS

Common side effects are headache, fatigue, drowsiness, nausea, dry mouth and gastrointestinal disturbances.

# **USE IN PREGNANCY AND LACTATION**

US FDA pregnancy category of Fexofenadine Hydrochloride is C. So, Fexofenadine Hydrochloride should be avoided in pregnancy and lactation unless the potential benefits to the other outweigh the possible risks to the fetus

# **USE IN CHILDREN AND ADOLESCENTS**

Safety and effectiveness of Fexofenadine in paediatric patient under the age of 6 months have not been established.

# DRUG INTERACTIONS

Plasma concentration of Fexofenadine Hydrochloride has been increased when given with Erythromycin or Ketoconazole. Aluminium and Magnesium Hydroxide containing antacid reduces the absorption of Fexofenadine Hydrochloride.

### **OVERDOSAGE**

An accidental consumption of very high dose should be treated symptomatically together with the necessary supportive measures.

### **STORAGE**

Store below 30°C temperature in a cool & dry place. Protect from light & moisture. Keep out of the reach of children.

# **HOW SUPPLIED**

Fexten 120 Tablet: Each box contains 30 tablets in Alu-Alu blister pack. Fexten Suspension: Each Amber PET bottle contains 50 ml suspension.

