

Fenadin®

(Fexofenadine Hydrochloride USP)

DESCRIPTION:

Fenadin® 60 : Each tablet contains Fexofenadine Hydrochloride 60mg

Fenadin® 120 : Each tablet contains Fexofenadine Hydrochloride 120mg

Fenadin® 180 : Each tablet contains Fexofenadine Hydrochloride 180mg

Fenadin® 50mL/30mL suspension : Each 5ml suspension contains Fexofenadine Hydrochloride 30mg

INDICATIONS & USAGE:

Seasonal Allergic Rhinitis

Fenadin® is indicated for the relief of symptoms associated with seasonal allergic rhinitis in adults and children 2 years of age and older. Symptoms treated effectively include

- Sneezing
- Rhinorrhea
- Itchy & Watery nose and throat
- Itchy skin
- Red eyes

Chronic Idiopathic Urticaria

Fenadin® is also indicated for the treatment of uncomplicated skin manifestations of chronic idiopathic urticaria in adults and children 6 months to 11 years of age.

DOSAGE AND ADMINISTRATION:

Fenadin® Tablet

Seasonal Allergic Rhinitis

Adults and children 12 years and older : The recommended dose of **Fenadin®** is 60mg twice daily, or 120mg or 180mg once daily. A dose of 60mg once daily is recommended as the starting dose in patients with decreased renal function.

Children 6 to 11 years : The recommended dose of **Fenadin®** 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 **Fenadin®** is 60mg twice daily. A dose of 60mg once daily is recommended as the starting dose in patients with decreased renal function.

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

Fenadin® oral Suspension

Seasonal Allergic Rhinitis

Children 2 to 11 years : The recommended dose of **Fenadin®** oral suspension is 30mg twice daily. A dose of 30mg (5ml) once daily is recommended as the starting dose in pediatric patients with decreased renal function.

Shake the bottle well, before each use.

Chronic Idiopathic Urticaria

Children 6 months to 11 years : The recommended dose of **Fenadin®** oral suspension is 30mg (5ml) twice daily for patients 2 to 11 years of age and 15mg (2.5ml) 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 **Fenadin®** oral suspension are 30mg (5ml) once daily for patients 2 to 11 years of age and 15mg (2.5ml) once daily for patients 6 months to less than 2 years of age.

Shake the bottle well, before each use.

Age group	Fenadin Tablet	Fenadin Suspension
Adults and Children ≥12 years	120mg once daily* or 180mg once daily+ or 60mg twice daily*	N/A
Children 6 to 11 years 2 to 5 years 6 months to less than 2 years	30mg twice daily* N/A N/A	30mg (1tsp) twice daily* 30mg (1tsp) twice daily* 15mg (1/2 tsp) twice daily*¥

* Starting dose in patients with decreased renal function should be the recommended dose indicated above but administered once daily.

+ Dose not for use in patients with decreased renal function.

¥ Indicated for chronic idiopathic urticaria only.

SIDE EFFECTS:

The incidence of adverse events, including drowsiness, is not dose related and is similar across subgroups defined by age, gender and race. The other side effects are Viral like infection (cold, flu), nausea, dysmenorrhea, fatigue, headache and throat irritation.

DRUG INTERACTION:

Fenadin® should not be taken closely in time with aluminum and magnesium containing antacid, erythromycin or ketoconazole co-administration may enhance Fexofenadine absorption.

CONTRAINDICATION:

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

PREGNANCY:

There are no adequate and well-controlled studies in pregnant women. **Fenadin®** should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

NURSING MOTHERS:

No adverse effects have been seen in breast feeding infants whose mothers were receiving Fexofenadine Hydrochloride and **THE AMERICAN ACADEMY OF PEDIATRICS** considers that it is therefore usually compatible with breast feeding.

PEDIATRIC USE:

Safety and effectiveness of Fexofenadine Hydrochloride in pediatric patients can be used up to the age of 6 months.

STORAGE:

Store in a cool and dry place, away from light & children.

PACKAGE QUANTITIES:

Fenadin® 60 : Each box Containing 1X10's / 3X10's film coated tablets in blister strips.

Fenadin® 120 : Each box Containing 2X10's / 5X10's film coated tablets in blister strips.

Fenadin® 180 : Each box Containing 2X10's film coated tablets in blister strips.

Fenadin® 50mL suspension : Each bottle containing 50mL suspension, 5mL spoon and 5mL dropper.

Fenadin® 30mL suspension : Each bottle containing 30mL suspension and 2.5mL dropper.

® Trade Mark

Only Fenadin® 30mL & 50mL suspension

Manufactured by:

Ziska Pharmaceuticals Ltd. for



RENATA LIMITED

Mirpur, Dhaka, Bangladesh