Dinafex®

Fexofenadine Hydrochloride USP Film Coated Tablet & Suspension

DESCRIPTION

Dinafex® is a preparation of Fexofenadin Hydrochloride. It is an orally active non-sedating H_1-receptor antagonist and is effective for the relief of symptoms associated with allergic rhinitis. It inhibits antigen-induced bronchospasm. Fexofenadine Hydrochloride is rapidly absorbed after oral doses with peak plasma concentrations being reached in 1-3 hours. It is about 60% to 75% bound to plasma proteins.

INDICATIONS

- Relief of symptoms associated with seasonal allergic rhinitis
- Relief of symptoms associated with chronic idiopathic urticaria
- Relief of symptoms associated with perennial allergic rhinitis

DOSAGE & ADMINISTRATION

Patient Population	Dinafex® tablets	Dinafex® oral suspension
Adults and children >12 years	60 mg twice daily[1] or 120 mg once daily or 180 mg once daily[2]	N/A
Children 6 to 11 years	30 mg twice daily[1]	30 mg (1 teaspoon or 5 mL) twice daily[1]
Children 2 to 5 years	N/A	30 mg (1 teaspoon or 5 mL) twice daily[1]
Children 6 months to less than 2 years	N/A	15 mg (½ teaspoon or 2.5 mL) twice daily[1,3]

[1] starting dose in patients with decreased renal function should be the recommended dose indicated above but administered once daily

[2] dose not for use in patients with decreased renal function

[3] indicated for chronic idiopathic urticaria only

CONTRAINDICATIONS

Dinafex® is contraindicated in patients with known hypersensitivity to active ingredient.

SIDE-EFFECTS

Common side effects are abdominal discomfort, diarrhoea, nausea & vomiting, headache, back pain, dizziness & pain in extremity.

DRUG INTERACTIONS

Fexofenadine Hydrochloride should not be taken closely in time with aluminium and magnesium containing antacids. Co-administration of Fexofenadine Hydrochloride with either ketoconazole or erythromycin led to increased plasma concentrations of fexofenadine in healthy adult subjects. Fruit juices such as grapefruit, orange and apple may reduce the bioavailability and exposure of Fexofenadine.

USE IN PREGNANCY & LACTATION

Pregnancy Category C

There are no adequate and well-controlled studies in pregnant women. Fexofenadine Hydrochloride should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. It is not known whether or not Fexofenadine Hydrochloride is excreted in human breast milk. There are no adequate and well-controlled studies in women during lactation.

PHARMACEUTICAL PRECAUTION

Dinafex® Tablet: Do not store above 30 °C temperature. Keep away from light and wet place. Keep out of reach of children.

Dinafex® Suspension: Do not store above 25 °C temperature. Keep away from light and wet place. Keep out of reach of children.

PACKAGING

Dinafex® 60 mg Tablet : Box containing 4 strips of 10 tablets. Each film coated tablet contains Fexofenadine Hydrochloride USP 60 mg.

Dinafex® 120 mg Tablet : Box containing 4 strips of 10 tablets. Each film coated tablet contains Fexofenadine Hydrochloride USP 120 mg.

Dinafex® 180 mg Tablet : Box containing 4 strips of 10 tablets. Each film coated tablet contains Fexofenadine Hydrochloride USP 180 mg.

Dinafex® Suspension : Bottle containing 50 mL suspension. Each 5 mL contains Fexofenadine Hydrochloride USP 30 mg.

SK+F

Manufactured by

ESKAYEF PHARMACEUTICALS LTD.

TONGI, GAZIPUR, BANGLADESH

® REGD.TRADEMARK

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