For the use only of a Registered Medical Practitioner or Hospital or a Laboratory

ALLEGRA®

Fexofenadine Hydrochloride I.P.

Abridged Prescribing Information

COMPOSITION

Oral Suspension

Each 5ml of Allegra suspension contains Fexofenadine hydrochloride I.P. 30mg.

Tablets

Each tablet of Allegra 30mg contains Fexofenadine hydrochloride I.P. 30mg (equivalent to fexofenadine 28mg);

Each tablet of Allegra 120mg contains Fexofenadine hydrochloride I.P. 120mg (equivalent to fexofenadine 112mg);

Each tablet of Allegra 180mg contains Fexofenadine hydrochloride I.P. 180mg (equivalent to fexofenadine 168mg)

THERAPEUTIC INDICATIONS

Allegra is indicated for relief of symptoms associated with allergic rhinitis and chronic idiopathic urticaria. Allegra oral suspension is indicated for relief of symptoms associated with allergic rhinitis in children 2-11 years of age and uncomplicated skin manifestations of chronic idiopathic urticaria in children 6 months to 11 years of age.

DOSAGE AND ADMINISTRATION

Allergic rhinitis

Children 2-11 years:

Recommended dose is 30mg twice daily. A dose of 30mg (5ml in case of Allegra Suspension) once daily is recommended as the starting dose for paediatric patients with decreased renal function.

Adults and children aged 12 years and over:

Recommended dose is 120mg once daily or 180mg once daily. A dose of 60 mg once daily is recommended as the starting dose in patients with decreased renal function.

Allergic skin conditions (eg. Chronic urticaria)

Children 6 months -11 years:

Recommended dose is 30mg (5ml) twice daily for patients 2-11 years of age and 15mg (2.5ml) twice daily for patients 6 months to less than 2 years of age. For paediatric patients with decreased renal function the recommended starting dose is 30mg (5ml) once daily for patients 2-11 years of age and 15mg (2.5ml) once daily for patients 6 months to less than 2 years of age

Adults and children aged 12 years and over: Recommended dose is 180mg once daily. A dose of 60 mg once daily is recommended as the starting dose in patients with decreased renal function.

Special Populations

Studies in special risk groups (elderly or hepatically impaired patients) indicate that it is not necessary to adjust the dose of fexofenadine hydrochloride in these patients.

SAFETY-RELATED INFORMATION

Contraindications: Product is contraindicated in patients with known hypersensitivity to any of its ingredients.

Precautions: Patients should be advised to shake the Allegra suspension bottle well, before each use.

Pregnancy: Used only if the potential benefit outweighs the potential risk.

Interactions : Coadministration of fexofenadine with erythromycin or ketoconazole resulted in no significant increases in QTc. Administration of an antacid containing aluminium or magnesium hydroxide gels should be 2 hours before or after administration of fexofenadine. No interaction between fexofenadine and omeprazole observed.

Adverse Reactions: Most frequent include: >3% headache, 1-3% drowsiness, dizziness and nausea.

For full prescribing information please write to : Sanofi India Ltd., Sanofi House, CT Survey No 117-B, L&T Business Park, Saki Vihar Road, Powai, Mumbai 400072

Source: CCDS Ver. 5, NOV 2006,USPI-July 2007
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