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

**Abridged Prescribing Information**

ALLEGRA®
**Fexofenadine Hydrochloride I.P.**

**COMPOSITION**
**Fexofenadine Hydrochloride Suspension**
Each 5ml (teaspoonful)n contains Fexofenadine hydrochloride I.P. 30mg.
In flavoured syrup base

**Fexofenadine Hydrochloride Tablets IP 120mg and 180mg**
Each film-coated tablet contains Fexofenadine hydrochloride I.P. 120mg
Each film-coated tablet contains Fexofenadine hydrochloride I.P. 180mg

**THERAPEUTIC INDICATIONS**
Allegra® 120mg and 180mg tablets are indicated for relief of symptoms associated with allergic rhinitis and chronic idiopathic urticaria. Allegra® 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.
**Adults and children aged 12 years and over:** Recommended dose is 180mg once daily.
**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. P-gp inducers (such as apalutamide) may reduce the exposure of fexofenadine. A clinical drug-drug interaction study showed that co-administration of apalutamide and a single oral dose of 30 mg fexofenadine resulted in a 30 % decrease in AUC and 7 % in Cmax of fexofenadine.
**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

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