

## **Abridged Prescribing Information**

### **ALLEGRA D®**

Fexofenadine HCL 60mg + Pseudoephedrine HCL 120mg ER Tablets U.S.P.

### **COMPOSITION**

Each Extended-Release tablet contains: Fexofenadine Hydrochloride IP - 60 mg, Pseudoephedrine Hydrochloride IP -120mg

### **THERAPEUTIC INDICATIONS**

Allegra D is indicated for the relief of symptoms associated with allergic rhinitis in adults and children 12 years of age and older. Symptoms treated effectively include sneezing, rhinorrhea, itchy nose/palate/and/or throat, itchy/watery/red eyes, and nasal congestion.

Allegra D is administered when both the antihistaminic properties of fexofenadine hydrochloride and the nasal decongestant properties of pseudoephedrine hydrochloride are desired.

### **DOSAGE AND ADMINISTRATION**

The recommended dose of Allegra D is one tablet twice daily for adults and children 12 years of age and older. It is recommended that the administration of Allegra D with food should be avoided. A dose of one tablet once daily is recommended as the starting dose in patients with decreased renal function.

#### **Special Populations**

Allegra D is used in pregnancy or lactation only if the potential benefit justified the potential risk to the fetus or nursing infants.

### **SAFETY-RELATED INFORMATION**

#### **Contraindications**

Allegra D is contraindicated in-patients with known hypersensitivity to any of its ingredients.

Allegra D tablets (pseudoephedrine component) are contraindicated in patients taking monoamine oxidase inhibitors and for 14 days after stopping use of a MAO inhibitor.

#### **Warnings/Precautions**

Sympathomimetic amines (Due to its pseudoephedrine component) is used judiciously and sparingly in patients with hypertension, diabetes mellitus, ischemic heart disease, increased intraocular pressure, hyperthyroidism, renal impairment, or prostatic hypertrophy.

#### **Pregnancy/Lactation**

Used only if the potential benefit outweighs the potential risk.

#### **Interactions**

Fexofenadine hydrochloride and pseudoephedrine hydrochloride do not influence the pharmacokinetics of each other when administered concomitantly.

No differences in adverse events or QTc interval when fexofenadine hydrochloride alone or in combination with erythromycin or ketoconazole is administered.

Fexofenadine had no effect on the pharmacokinetics of erythromycin or ketoconazole.

No interaction between fexofenadine and omeprazole was observed.

P-gp inducers (such as apalutamide) may reduce the exposure of fexofenadine.

Concomitant use with antihypertensive drugs (eg, methyldopa, mecamlamine and reserpine), may reduce their anti-hypertensive effects.

Increased ectopic pacemaker activity can occur when pseudoephedrine is used concomitantly with digitalis.

Care should be taken in the administration of Allegra D concomitantly with other sympathomimetic amines because combined effects on the cardiovascular system may be harmful to the patient.

#### **Adverse Reactions**

Predominately - insomnia, headache, nausea, dry mouth, dizziness, agitation, nervousness, anxiety and palpitation.

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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