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

Abridged Prescribing Information

ALLEGRA D®
Fexofenadine HCL 60mg + Pseudophedrine HCL 120mg ER Tablets IP

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.
Risk of abuse:
Pseudoephedrine carries the risk of abuse. Increased doses may ultimately produce toxicity. Continuous use can lead to tolerance resulting in an increased risk of overdosing. The recommended maximum dose and treatment duration should not be exceeded (Posology and Method of Administration).
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, mecamylamine 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: M/s. Sanofi Consumer Healthcare India Limited, Unit 1104, 11th Floor, Godrej Two, Pirojshanagar, Eastern Express Highway, Vikhroli East, Mumbai, Maharashtra, 400079

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