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

ALLEGRA® M Tablets

Fexofenadine Hydrochloride I.P. and Montelukast Sodium I.P.

COMPOSITION

Each film coated tablet contains: Fexofenadine hydrochloride I.P. 120 mg, Montelukast Sodium I.P. 10 mg

THERAPEUTIC INDICATIONS

ALLEGRA® M tablets are indicated for the treatment of allergic rhinitis in adults.

DOSAGE AND ADMINISTRATION:

Adults: One tablet once daily for oral administration

SAFETY-RELATED INFORMATION

Contraindications: ALLEGRA®M tablets are contraindicated in patients with a known hypersensitivity to montelukast, fexofenadine or to any of the excipients.

Warnings and Precautions: Patients should be advised never to use oral montelukast to treat acute asthma attacks and to keep their usual appropriate rescue medication for this purpose readily available. If an acute attack occurs, a short-acting inhaled beta-agonist should be used. Montelukast should not be substituted abruptly for inhaled or oral corticosteroids. In rare cases, patients on therapy with anti-asthma agents including montelukast may present with systemic eosinophilia, sometimes presenting with clinical features of vasculitis consistent with Churg-Strauss syndrome, which is often treated with systemic corticosteroid therapy. These cases have been sometimes associated with the reduction or withdrawal of oral corticosteroid therapy. Physicians should be alert to eosinophilia, vasculitic rash, worsening pulmonary symptoms, cardiac complications, and/or neuropathy presenting in their patients. Patients who develop these symptoms should be reassessed and their treatment regimens evaluated. Treatment with montelukast does not alter the need for patients with aspirin-sensitive asthma to avoid taking aspirin and other non-steroidal anti-inflammatory drugs. Neuropsychiatric events have been reported in adults, adolescents, and children taking Montelukast (see section Adverse reactions). Patients and physicians should be alerted for neuropsychiatric events. Patients and/or caregivers should be instructed to notify their physician if these changes occur. Prescribers should carefully evaluate the risks and benefits of continuing treatment with Montelukast if such events occur. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

Effects on ability to drive and use machines: ALLEGRA® M has no or negligible influence on the ability to drive and use machines. However, individuals have reported drowsiness or dizziness.

Pregnancy and Lactation: There are no studies in pregnant and lactating women. Allegra® M should be used in pregnancy and nursing women only if the potential benefit outweighs the potential risk to the foetus/infants.

Adverse Reactions: Common side effects include: **Fexofenadine –** headache, drowsiness, dizziness and nausea.

Montelukast - upper respiratory infection, diarrhoea, nausea, vomiting, elevated levels of serum transaminases (ALT, AST), pyrexia and rash.

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

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Source:

Fexofenadine: CCDS v7 dated 28th Sept 2023

Montelukastst CCDS v1 dated 04th Feb 2021