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.

THERAPEUTIC CATEGORY

Antihistamine and leukotriene receptor antagonist

COMPOSITION

Each film coated tablet contains:
Fexofenadine hydrochloride I.P. …….... 120 mg
Montelukast Sodium equivalent to Montelukast I.P…….. 10 mg
Excipients..... q.s.
Colour: Yellow oxide of iron and Titanium Dioxide

THERAPEUTIC INDICATIONS

ALLEGRA™ M tablets are indicated for the treatment of allergic rhinitis in adults and adolescents 15 years of age and older.

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. 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

Created: Oct 2012
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Source:

Fexofenadine: CCDS, Ver.5, dated Feb 2006
Montelukast:
Singulair (Merck) dated October 2012
Singulair (Merck Sharp & Dohme Limited) dated October 2018
https://www.medicines.org.uk/emc/product/198/smpc/history
Dated 11.10.2018