

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

COMPOSITION

Each film coated tablet contains:

Fexofenadine hydrochloride I.P. 120 mg
Montelukast Sodium equivalent to Montelukast I.P. 10 mg
Excipients..... q.s.

THERAPEUTIC INDICATIONS

ALLEGRA[™] M tablets are indicated for the treatment of allergic rhinitis in adults only.

DOSAGE AND ADMINISTRATION:

Adults: One tablet once daily

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: *Eosinophilic Conditions:* In rare cases, patients on therapy with montelukast may present with systemic eosinophilia, sometimes exhibiting clinical features of vasculitis consistent with Churg-Strauss syndrome. Physicians should be alert to eosinophilia, vasculitic rash, worsening pulmonary symptoms, cardiac complications, and/or neuropathy presenting in their patients. *Neuropsychiatric Events:* Neuropsychiatric events such as agitation, aggressive behaviour or hostility, anxiousness, depression, dream abnormalities, hallucinations, insomnia, irritability, restlessness, somnambulism, suicidal thinking and behaviour (including suicide), and tremor have been reported in patients taking montelukast. *Aspirin Sensitivity:* Patients with known aspirin sensitivity should continue avoidance of aspirin or non-steroidal anti-inflammatory agents while taking montelukast. *Concomitant Corticosteroid Use:* Montelukast should not be abruptly substituted for inhaled or oral corticosteroids. *Acute Asthma:* Montelukast is not indicated for use in the reversal of bronchospasm in acute asthma attacks including status asthmaticus.

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.

Adverse Reactions: Common side effects include:

Fexofenadine – headache, drowsiness, dizziness and nausea.

Montelukast - dyspepsia, abdominal pain, rash, dizziness, headache, fatigue, fever, trauma, cough and nasal congestion

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

Source: Fexofenadine CCDS, Ver.5, dated Feb 2006

MONTAIR FX Tablets (Cipla) dated December 2010

Singulair (Merck) dated October 2012