

Airmont

Montelukast USP

Composition: Airmont 10 Tablet: Each tablet contains Montelukast Sodium USP equivalent to Montelukast 10 mg.

Pharmacology: Montelukast is a selective & orally active leukotriene receptor antagonist that inhibits the cysteinyl leukotriene CysLT1 receptor. Cysteinyl leukotriene receptor occupation have been correlated with the pathophysiology of asthma (such as, airway edema, smooth muscle contraction & altered cellular activity associated with the inflammatory process, which contribute to the signs & symptoms of asthma).

Indication: Montelukast is indicated for the prophylaxis & chronic treatment of asthma in adults & pediatric patients.

Dose & administration:

Pediatric patients (6 months- 5 years of age): One 4 mg tablet in the evening.

Pediatric patients (6-14 years of age): One 5 mg tablet in the evening.

Adolescents & adults (15 years of age or older): One 10 mg tablet in the evening.

Contraindication: Montelukast is contraindicated to patients with hypersensitivity to any component of this product.

Warning & precaution: Montelukast is not indicated for use in the reversal of bronchospasm in acute asthma attacks (in case of status asthmaticus).

Patients with known aspirin sensitivity should continue avoidance of aspirin or other NSAID, while taking Montelukast. In rare cases, patients on therapy with Montelukast may present with systemic eosinophilia, sometimes presenting with clinical features of vasculitis consistent with churg-strauss syndrome, a condition which is often treated with systemic corticosteroid therapy. Physician should be alert to eosinophilia, Vasculitic rash, worsening pulmonary symptoms, cardiac complications, and/or neuropathy presenting in their patients. A casual association between Montelukast & these underlying conditions has not been established.

Side effects: Generally, Montelukast is well-tolerated. Side effects include dizziness, headache, diarrhea, restlessness, abdominal pain, cough, fever, asthenia, rash & upper respiratory tract infection.

Use in pregnancy & lactation: Pregnancy: There are no adequate & well-controlled studies of Montelukast in pregnant woman. Because animal reproductive studies are not always predictive of human response, so Montelukast should be used during pregnancy only if clearly needed.

Lactation: It is not known if Montelukast is excreted in human milk. Because many drugs are excreted in human milk, so caution should be exercised when Montelukast is given to a nursing mother.

Use in children & adolescents: Safety & efficacy of Montelukast has been established in adequate & well controlled studies in pediatric patients with asthma & allergic rhinitis between age 1 to 14 years.

Drug Interaction: Montelukast has been administered with other therapies routinely used in the prophylaxis & chronic treatment of asthma with no appropriate increase in adverse reactions. Cytochrome P-450 inducers; Although Phenobarbital induces hepatic metabolism, no dose adjustment for Montelukast is recommended. It is reasonable to employ appropriate clinical monitoring when potent Cytochrome P-450 enzyme inducers, such as Phenobarbital or Rifampin, are co-administered with Montelukast.

Overdose: There were no adverse experiences reported in the majority of overdosage reports. The most frequent adverse experiences observed were thirst, mydriasis, hyperkinesia & abdominal pain. In the event of overdose, it is reasonable to employ the usual supportive measures; e.g., remove unabsorbed material from the gastrointestinal tract, employ clinical monitoring, & institute supportive therapy, if required.

Storage: Store below 30 °C & in a dry place. Keep away from light. Keep all medicines out of the reach of children.

Packing: Airmont 10 Tablet: Each box contains 3X10's tablets in alu-alu blister pack.



Manufactured by:

Goodman Pharmaceuticals Ltd.

Better Health For All
Bhangnahati, Sreepur, Gazipur, Bangladesh