

Silmon[®]

Montelukast

Composition:

Silmon[®] 10 Tablet : Each film coated tablet contains Montelukast Sodium USP equivalent to Montelukast 10 mg.

Description:

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

Indications:

Montelukast is indicated for the prophylaxis and chronic treatment of asthma in adults and pediatric patients.

Dosage & Administration:

Adults (15 years of age or over): 10 mg daily to be taken in the evening.

Elderly: Normal adult dose is recommended.

Children (6-14 years of age): 5 mg daily to be taken in the evening.

The safety and efficacy of Montelukast was demonstrated in clinical trials where it was administered in the evening without regard to the time of food ingestion.

Side Effects:

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

Use in Special Group:

Pregnancy: There are no adequate and well-controlled studies of Montelukast in pregnant women. 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.

Pediatric use: Safety & efficacy of Montelukast have been established in adequate & well-controlled studies in paediatric patients with asthma 6 month to 14 years of age. Safety & efficacy profiles in this age group are similar to those seen in adults.

Contraindications:

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

Warning & Precautions :

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 neuropathy presenting in their patients. A causal association between Montelukast and these underlying conditions has not been established.

Drug Interactions:

Montelukast has been administered with other therapies routinely used in the prophylaxis and chronic treatment of asthma with no appropriate increase in adverse reactions.

Cytochrome P-450 inducers: Although Phenobarbital induces hepatic metabolism, no dosage 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.

Storage:

Store at temperature not exceeding 30° C in a dry place. Protect from light & moisture. Keep out of the reach of children.

Commercial Pack:

Silmon[®] 10 : Each box contains 3x10 tablets in Alu-Alu blister pack.

Manufactured by:
 **Silva**
Pharmaceuticals Limited
Majidee, Noakhali, Bangladesh

04-07-154