Odmon®

Montelukast Sodium

Presentation:

Odmon®5 Chewable Tablet: Each tablet contains Montelukast Sodium equivalent to Montelukast 5mg.

Odmon®10 Tablet: Each tablet contains Montelukast Sodium equivalent to Montelukast 10mg.

Description:

Montelukast is a selective and orally active leukotriene receptor antagonist that inhibits the Cysteinyl leukotriene $CysLT_1$ receptor. Cysteinyl leukotriene 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 and Uses:

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

Dosage and Administration:

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

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

Children (6months- 5years): 4mg 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.

Contraindication:

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

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 vaculitis 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 and these underlying conditions has not been established.

Use in pregnancy and lactation

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, so caution should be exercised when Montelukast is given to a nursing mother.

Drug Interaction:

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.

Overdosage:

There were no adverse experiences reported in the majority of overdosage reports. The most frequent adverse experiences observed were thirst, mydriasis, hyperkinesias, and 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, and institute supportive therapy, if required.

Storage condition:

Store in a cool and dry place, away from light.
Keep all medicines out of the reach of children.

Commercial Packs:

Odmon®5: Each box contains 1X10's chewable tablets in Alu- Alu blister strip

Odmon®10: Each box contains 2X10's tablets in Alu-Alu blister strip

Manufactured by
Renata Limited
Mirpur, Dhaka, Bangladesh