Tekast®

Montelukast USP

COMPOSITION:

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

Tekast ® 5 Tablet: Each chewable tablet contains Montelukast Sodium USP equivalent to 5 mg Montelukast.

PHARMACOLOGY:

Tekast ® Tablet (Montelukast) is a selective and orally active leukotriene receptor antagonist that inhibits the cysteinyl leukotriene receptor (CysLT1). The cysteinyl leukotrienes (LTC4, LTD4, LTE4) are product of arachidonic acid metabolism and are released from various cells, including mast cells and eosinophils. Cysteinyl leukotrienes and leukotriene receptor occupation have been correlated with the pathophysiology of asthma, including airway edema, smooth muscle contraction and altered cellular activity associated with the inflammatory process which contribute to the signs and symptoms of asthma.

INDICATION:

Tekast ® Tablet is indicated for the prophylaxis and chronic treatment of asthma in adults and children.

DOSE & ADMINISTRATION:

Age	Dose
6 months - 6 years	4mg/day, in the evening
6 years - 15 years	5mg/day, in the evening
15 years and older	10mg/day, in the evening

Tekast ® Tablet (Montelukast) may be taken With or Without food. OR AS DIRECTED BY THE PHYSICIAN.

CONTRA-INDICATION:

Montelukast is contraindicated in patients who are hypersensitive to any component of this product.

WARNING AND PRECAUTION:

Montelukast is not indicated for use in acute asthma attacks. Therapy with montelukast can be continued during acute exacerbations of asthma. Montelukast should not be used as monotherapy for the treatment and management of exercise-induced bronchospasm.

SIDE EFFECTS:

Montelukast has been generally well tolerated. Side effects, which usually are mild, including gastro-intestinal disturbances, dry mouth, thirst; hypersensitivity reactions including anaphylaxis, angioedema and skin reactions; asthenia, dizziness, irritability, restlessness, headache, sleep disorders (insomnia, drowsiness, nightmares); upper respiratory tract infection, fever, arthralgia, myalgia. The overall incidence of side effects reported with montelukast was comparable to placebo.

USE IN PREGNANCY & LACTATION:

There are no adequate and well controlled studies in pregnant women. Montelukast should be used during pregnancy only if clearly needed. Montelukast is excreted in milk. So caution should be exercised when montelukast is given to a nursing mother.

USE IN CHILDREN & ADOLESCENTS:

Pediatric use: Safety and efficacy of Montelukast has been established in adequate and well controlled studies in pediatric patients with asthma and allergic rhinitis between ages 1 to 14 years. Long term trials evaluating the effect of chronic administration of Montelukast on linear growth in pediatric patients have not been conducted.

Geriatric use: Of the total number of subjects in clinical studies of Montelukast, 3.5% were 65 years of age and over 0.4% were 75 years of age and over. No overall differences in safety or effectiveness were observed between these subjects and younger subjects. But greater sensitivity of some older individuals cannot be ruled out.

DRUG INTERACTION:

It is reasonable to employ appropriate clinical monitoring when potent cytochrome P450 enzyme inducers such as Phenobarbital or Rifampin are co-administered with Montelukast.

OVERDOSE:

Symptoms: Abdominal pain, somnolence, thirst, headache, vomiting, and psychomotor hyperactivity.

Management: Supportive and symptomatic treatment. If indicated, unabsorbed material should be removed from the GI tract.

STORAGE:

Store in a dry and cool place below 30^0 C temperature and keep away from light and moisture. Keep out of reach of children.

PACKING:

Tekast ® 5 Tablet: Each box contains 2x10's tablet in Alu-Alu blister pack.

Tekast ® 10 Tablet: Each box contains 3x10's tablet in Alu-Alu blister pack.

Manufactured by
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