

Monteluk

Montelukast INN

Description

The cysteinyl leukotrienes (LTC₄, LTD₄, LTE₄) are products of arachidonic acid metabolism and are released from various cells, including mast cells and eosinophils. These Eicosanoids bind to cysteinyl leukotriene receptors (CysLT) found in the human airway. Montelukast is an orally active compound that binds with high affinity and selectivity to the CysLT₁ receptor. Montelukast inhibits physiologic actions of LTD₄ at the CysLT₁ receptor without any agonist activity.

Composition

Monteluk 5 mg Tablet: Each film-coated tablet contains Montelukast Sodium INN equivalent to Montelukast 5 mg.

Monteluk 10 mg Tablet: Each film-coated tablet contains Montelukast Sodium INN equivalent to Montelukast 10 mg.

Indication

Monteluk (Montelukast) is indicated in the treatment of asthma as add-on therapy in those patients with mild to moderate persistent asthma who are inadequately controlled on inhaled corticosteroids and in whom 'as needed' short-acting β -agonists provide inadequate clinical control of asthma. 10 mg tablet only: Asthmatic patients in whom Monteluk is indicated in asthma, it can also provide symptomatic relief of seasonal allergic rhinitis. Monteluk is also indicated in the prophylaxis of asthma in which the predominant component is exercise-induced bronchoconstriction.

Dosage & Administration

10 mg Tablet: The dosage for adults 15 years of age and older with asthma, or with asthma and concomitant seasonal allergic rhinitis, is one 10 mg tablet daily to be taken in the evening.

5 mg Tablet: The dosage for paediatric patients 6-14 years of age is one 5 mg tablet daily to be taken in the evening.

Side Effect

Montelukast appears to be well tolerated. The most common adverse effect reported was headache, occurring rash, dyspepsia, dizziness, and abdominal pain were all reported. A small percentage of pediatric patients have experienced diarrhea, sinusitis and otitis media.

Contra-Indication

Hypersensitivity to any component of this product.

Drug Interaction

Montelukast may be administered with other therapies routinely used in the prophylaxis and chronic treatment of asthma. In drug-interactions studies, the recommended clinical dose of montelukast did not have clinically important effects on the following medicinal products: theophylline, prednisone, prednisolone, oral contraceptives, terfenadine, digoxin and warfarin.

Caution should be exercised, particularly in children, when montelukast is co-administered with phenytoin, phenobarbital and rifampicin.

Precaution

Montelukast is not indicated for use the reversal of bronchospasm in acute asthma attacks, including status asthmaticus.

Use in Pregnancy and Lactation

Montelukast is classified as pregnancy category B. The drug has been shown to cross the placenta of pregnant rats and rabbits, but there have been no reports of its use in pregnant women. Montelukast is also known to be excreted into breast-milk, but only limited information is available on the significance of this finding. Caution should be used prior to initiating montelukast therapy in nursing mothers.

Storage

Store in a cool and dry place. Protect from light and moisture. Keep out of reach of children.

How Supplied

Monteluk 5 mg Tablet : Box Containing 1 X 10 tablets in Alu-Alu blister pack.

Monteluk 10 mg Tablet : Box Containing 3 X 10 tablets in Alu-Alu blister pack.

Manufactured by:

