

Only for the use of Medical Professionals

Reversair[®]

Montelukast Sodium

Description

Reversair[®] is a preparation of Montelukast. It is a selective and orally active leukotriene receptor antagonist that inhibits the cysteinyl leukotriene (CysLT₁) receptor. Cysteinyl Leukotrienes have been correlated with the pathophysiology of asthma and allergic rhinitis. Cysteinyl Leukotrienes may cause airway edema, smooth muscle contraction and cellular activity associated with the inflammatory process, which contribute to the signs and symptoms of asthma. By blocking leukotrienes to bind with CysLT₁ receptor Montelukast improves asthma symptoms, helps control asthma and improves seasonal allergy symptoms.

Indications

Reversair[®] is indicated for the prophylaxis and chronic treatment of asthma.

Dosage and administration

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

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

Children (6 months-5 years of age): 4 mg daily to be taken in the evening.

Use in pregnancy and lactation

There are no adequate and well controlled studies of Montelukast in pregnant women. As animal reproductive studies are not always predictive of human response, Montelukast should be used in pregnancy only if clearly needed. It is not known if Montelukast is excreted in human milk. As many drugs are excreted in human milk, caution should be exercised when Montelukast is given to a nursing mother.

Side effects

Generally Montelukast is well tolerated. Side effects include abdominal pain, stomach or intestinal upset, fever, tiredness, dizziness, cough, dental pain, flu, stuffy nose, rash and upper respiratory tract infection.

Contraindications

Hypersensitivity to any component of this product.

Precautions

Montelukast is not indicated for use in the reversal of bronchospasm in acute asthma attack, status asthmaticus. Therapy with Montelukast can be continued in the acute exacerbations of asthma. While the dose of inhaled corticosteroid may be reduced gradually under medical supervision, Montelukast should not be abruptly substituted for inhaled or oral corticosteroids. Patients with known aspirin sensitivity should continue avoidance of aspirin or non-steroidal anti-inflammatory agents while taking Montelukast.

Drug interactions

Montelukast may be administered with other therapies routinely used in the prophylaxis and chronic treatment of asthma and in the treatment of allergic rhinitis.

In drug- interactions studies, the recommended clinical dose of Montelukast did not have clinically important effects on the pharmacokinetics of the following drugs: Theophylline, Prednisone, Prednisolone, Oral Contraceptives, Terfenadine, Digoxin, and Warfarin. The area under the plasma concentration-time curve (AUC) for Montelukast was decreased approximately 40% in subjects with co-administration of Phenobarbital. No dosage adjustment for Montelukast is recommended. 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

There were no adverse experiences in the majority of overdose reports. The most frequently occurring adverse experiences were consistent with the safety profile of Montelukast and included abdominal pain, somnolence, thirst, headache, vomiting and psychomotor hyperactivity.

Pharmaceutical Precautions

Store in a cool & dry place. Protect from light.

Presentation

Reversair[®] 10 mg tablet: Each tablet contains Montelukast 10 mg as Sodium INN.

Reversair[®] 5 mg orodispersible tablet : Each orodispersible tablet contains Montelukast 10 mg as Sodium INN.

Reversair[®] 4 mg orodispersible tablet : Each orodispersible tablet contains Montelukast 10 mg as Sodium INN.

Package quantities

Reversair[®] 10 mg tablet: Carton of 20's pack in Alu-Alu blister.

Reversair[®] 5 mg orodispersible tablet : Carton of 20's pack in Alu-Alu blister.

Reversair[®] 4 mg orodispersible tablet : Carton of 20's pack in Alu-Alu blister.

® Registered Trade Mark



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