Lumona®

Montelukast Sodium USP Film Coated Tablet

DESCRIPTION

Lumona® is a preparation of Montelukast Sodium. It is a selective and orally active leukotriene receptor antagonist that inhibits the cysteinyl leukotriene CysLT1 receptor. The cysteinyl leukotriens (LTC4, LTD4, LTE4) are products of arachidonic acid metabolism and are released from mast cells and eosinophils. These eicosanoids bind to cysteinyl leukotriens receptors (CysLT) found in human airway cysteinyl leukotriens and leukotriene receptor occupation that are responsible in pathophysiology of asthma and other inflammatory process for its sign and symptoms.

INDICATIONS

Lumona® is indicated for the prophylaxis and chronic treatment of asthma. It is also indicated for the relief of symptoms of seasonal and perennial allergic rhinitis.

DOSAGE AND ADMINISTRATION

Lumona® should be taken once daily. For asthma, the dose should be taken in the evening. For allergic rhinitis, the time of administration may be individualized to suit patient need. Patients with both asthma and allergic rhinitis should take only one tablet daily in the evening.

Adults and adolescents 15 years of age and older with asthma or allergic rhinitis: 10 mg tablet once daily in the evening.

CONTRAINDICATIONS

It is contraindicated in individuals who have known hypersensitivity to Montelukast or any of its components.

USE IN PREGNANCY AND LACTATION

There are, however, no adequate and well-controlled studies in pregnant women. Montelukast should be used during pregnancy only if clearly needed. It is not known whether 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.

PRECAUTIONS

Montelukast is not indicated for use in the reversal of bronchospasm in acute asthma attacks, including status asthmaticus. Patients should be advised to have appropriate rescue medication available. Therapy with Montelukast can be continued during 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. Montelukast should not be used as monotherapy for the treatment and management of exercise-induced bronchospasm. Patients with known aspirin sensitivity should continue avoidance of aspirin or non-steroidal anti-inflammatory agents while taking Montelukast.

SIDE-EFFECTS

Side-effects include headache, dizziness, heartburn, tiredness, abdominal pain, tooth pain, cough, fever, fatigue etc.

DRUG INTERACTIONS

Montelukast at a dose of 10 mg once daily did not cause clinically significant changes in the kinetics of a single intravenous dose of theophylline. It did not change the pharmacokinetic profile of warfarin (a substrate of cytochromes P450 3A4, 1A2 and 2C9) or influence the effect of a single 30 mg oral dose of warfarin on prothrombin time or the INR (International Normalized Ratio). Montelukast did not change the pharmacokinetic profile or urinary excretion of immunoreactive digoxin and the plasma concentration profile of terfenadine (a substrate of cytochrome P450 3A4) or fexofenadine, its carboxylated metabolite. It did not prolong the QTc interval following co-administration with terfenadine 60 mg twice daily.

PHARMACEUTICAL PRECAUTIONS

Do not store above 30 ˚C. Keep away from light and wet place. Keep out of reach of children.

PACKAGING

Lumona® 10 Tablet:

Box containing 3 strips of 14 tablets each. Each film coated tablet contains Montelukast Sodium USP equivalent to Montelukast 10 mg.

SK+F

Manufactured by

ESKAYEF PHARMACEUTICALS LTD.

TONGI, GAZIPUR, BANGLADESH

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