

MTS
Montelukast

COMPOSITION

MTS 10 mg tablets: Each film-coated tablet contains montelukast sodium USP 10 mg.

DESCRIPTION

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

INDICATIONS

MTS 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

MTS 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 patients' 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

Children 6 to 14 years of age with asthma or allergic rhinitis: 5 mg tablet once daily in the evening

Children 6 months to 5 years of age with asthma or allergic rhinitis: 4 mg tablet daily in the evening.

Safety and effectiveness in pediatric patients younger than 6 months of age with perennial allergic rhinitis and in patients less than 12 months of age with asthma have not been established yet.

CONTRAINDICATIONS

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

PRECAUTIONS

A 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. MTS 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.

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 if montelukast is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when montelukast is given to a nursing mother.

SIDE-EFFECTS

Side effects include headache, dizziness, heartburn, tiredness, stomach pain, tooth pain, cough, fever, sleep disorders, URTI 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 2A6 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

Keep away from light, store in a cool and dry place. Keep out of reach of children.

HOW SUPPLIED

MTS 10 mg tablets: Box containing 2 X 10's film coated tablets in Alu-alu blister pack.

Manufactured by



MEDICON Pharmaceuticals Ltd
Mirpur, Dhaka, Bangladesh.