

COMPOSITION

Montiva 4 Tablet : Each Oroflash tablet contains Montelukast Sodium BP equivalent to Montelukast 4 mg.

Montiva 5 Tablet : Each Oroflash tablet contains Montelukast Sodium BP equivalent to Montelukast 5 mg.

Montiva 10 Tablet : Each film coated tablet contains Montelukast Sodium BP equivalent to Montelukast 10 mg.

PHARMACOLOGY

Montelukast is a selective and orally active competitive cysteinyl leukotriene receptor antagonist, that inhibits the cysteinyl leukotriene (CysLT1) receptor to occupy the receptor. The cysteinyl leukotriene (CysLT1) receptor is found in the human airway with which cysteinyl leukotrienes bind to cause edema and smooth muscle contraction. Cysteinyl leukotrienes (CysLTs) have been correlated with the pathophysiology of asthma and allergic rhinitis.

INDICATION

Montelukast is indicated for the prophylaxis and chronic treatment of asthma, exercise-induced bronchoconstriction (EIB) and seasonal allergic rhinitis.

DOSAGE AND ADMINISTRATION

For adults and adolescents (15 years of age and older): 10 mg tablet once daily in the evening.

Children 6 - 14 years: 5 mg Oroflash tablet once daily in the evening.

Children 6 months - 5 years: 4 mg Oroflash tablet once daily in the evening.

CONTRAINDICATION

Montelukast is contraindicated to patients with hypersensitivity to any component of this product.

WARNING AND PRECAUTION

Montelukast is not indicated for use in the reversal of bronchospasm in acute asthma attacks. Montelukast should not be abruptly substituted for inhaled or oral corticosteroids. Patients with known aspirin sensitivity should avoid taking of aspirin or non-steroidal anti-inflammatory agents while taking Montelukast. Patients should be alert for neuropsychiatric events. Physician should be alert to eosinophilia, vasculitic rash, worsening pulmonary symptoms & cardiac complications presenting in their patients.

SIDE EFFECTS

Generally, Montelukast is well-tolerated. Side effects include fever, headache, cough, abdominal pain, diarrhea, otitis media, influenza, rhinorrhea & upper respiratory tract infection etc.

Moreover, mood-related changes or mental health side effects may occur that include depression, attention problems, restlessness, suicidal thoughts and actions, trouble sleeping etc.

USE IN PREGNANCY AND LACTATION

In Pregnancy: Montelukast is a pregnancy category B drug .There is no adequate and well-controlled studies in pregnant women. Montelukast should be used during pregnancy only if clearly needed.

In Lactation: It is not known if Montelukast is excreted in human milk. Caution should be exercised when Montelukast is given to a nursing mother.

DRUG INTERACTION

Montelukast has been administered with other therapies routinely used in the prophylaxis and chronic treatment of asthma. In drug-interaction studies, the recommended clinical dose of montelukast did not have clinically important effects on the pharmacokinetics of the following medical products: Theophylline, Prednisolone, Prednisone, oral Contraceptives, Terfenadine, Digoxin and Warfarin.

OVERDOSE

There were no adverse experiences reported in the majority of overdose reports. The most frequent adverse experiences observed were thirst, mydriasis, hyperkinesia, and abdominal pain. In the event of overdose, it is reasonable to employ the usual supportive measures; e.g. remove unabsorbed material from the gastrointestinal tract, employ clinical monitoring, and institute supportive therapy, if required.

STORAGE CONDITION

Keep in a cool and dry place below 30°C temperature, protected from light and moisture. Keep out of the reach of children.

HOW SUPPLIED

Montiva 4 Tablet : Each box contains 30 tablets in Alu-Alu blister pack.

Montiva 5 Tablet : Each box contains 30 tablets in Alu-Alu blister pack.

Montiva 10 Tablet : Each box contains 30 tablets in Alu-Alu blister pack.

Manufactured by:

NIPRO JMI Pharma Ltd.

Chauddagram, Cumilla, Bangladesh.