M-Kast
Tablet

DRUG INTERNATIONAL LTD.

Composition : **M-Kast 4 ODT :** Each Orodispersible Tablet Contains Montelukast USP 4mg.

M-Kast 5 ODT : Each Orodispersible Tablet Contains Montelukast USP 5mg.

M-Kast 10 : Each Tablet Contains Montelukast USP 10mg.

Pharmacology : Montelukast is a selective and orally active leukotriene receptor antagonist that inhibits the cysteinyl leukotriene receptor (CysLT). The cysteinylleukotrienes (LTC4, LTD4, LTE4) are products of arachidonic acid metabolism and are released from various cells, including mast cells and eosinophils. Cysteinylleukotrienes and leukotriene receptor occupation have been correlated with the pathophysiology of asthma & allergic rhinitis, including airway edema, smooth muscle contraction, and altered cellular activity associated with the inflaammatory process, which contribute to the signs and symptoms of asthma.

Indication : Montelukast Sodium is indicated for : 1. Prophylaxis and chronic treatment of asthma. 2. Acute prevention of Exercise-Induced Bronchoconstriction (EIB). 3. Relief of symptoms of Allergic Rhinitis (AR): Seasonal & Perennial Allergic Rhinitis.

Dosage & Administration : **Adults and adolescents with asthma or seasonal allergic rhinitis :** (The dosage for adults and adolescents 15 years of age and older): Montelukast 10 mg tablet once daily. **Pediatric patients with asthma or seasonal allergic rhinitis :** (The dosage for pediatric patients 6 to 14 years of age): Montelukast 5 mg tablet once daily. (The dosage for pediatric patients 2 years to 5 years of age): Montelukast 4 mg tablet once daily. (The dosage for pediatric patients 6 months to 5 years of age): Montelukast 4 mg once daily. This can be administered either directly in the mouth, or mixed with a spoonful of cold water or soft food at room temperature. Elderly use: The pharmacokinetic profile and the oral bioavailability of a single 10 mg oral dose of montelukast are similar in elderly and younger adults. The plasma half-life of montelukast is slightly longer in the elderly. No dosage adjustment in the elderly is required. Hepatic Insufficiency: No dosage adjustment is required in patients with mild-to-moderate hepatic insufficiency. Renal Insufficiency: No dosage adjustment is recommended in patients with renal insufficiency. Or, as directed by the registered physician.

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

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 Montelukastcan 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. Although Montelukast is eyectivein improving airway function in asthmatics with documented aspirin sensitivity, it has not been shown to truncatebronchoconstrictor response to aspirin and other non-steroidal anti-inflaammatory drugs in aspirin-sensitive asthmatic patients.

Side effects : Common: Diarrhea, fever, gastrointestinal discomfort, headache, nausea, vomiting, skin reactions, upper respiratory tract infection. Uncommon: Akathisia, anxiety, arthralgia, asthenia, abnormal behavior, depression, dizziness, drowsiness, dry mouth, hemorrhage, irritability, malaise, muscle complaints, oedema, seizure, abnormal sensation, sleep disorders. Rare: Angioedema, concentration impaired disorientation, eosinophilicgranulomatosis with polyangiitis, erythemanodosum, hallucination, hepatic disorders, memory loss, palpitations, pulmonary eosinophilia, suicidal tendencies, and tremor.

Use in Pregnancy and Lactation : Pregnancy category B. There are no adequate and well controlled studies in pregnant women. It should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. It is not known whether this medicine is excreted in human milk. However, other corticosteroids have been detected in human milk. Caution should be exercised when this medicine is administered to a nursing woman.

Use In Child : The safety and efficacy of Montelukast have been established in adequate and well-Controlled studies in pediatric patients with asthma 6 months to 14 years of age. Safety and efficacy in thisage group are similar to those seen in adults.

Drug-Interactions : Montelukast has been administered with other therapies routinely used in the prophylaxis and chronic treatment of asthma with no apparent increase in adverse reactions. In drug interaction 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 (norethindrone 1mg/ethinyl estradiol 35mcg), terfenadine, digoxin and warfarin. Although additional speci|c interaction studies were not performed, Montelukast was used concomitantly with a wide range of commonly prescribed drugs in clinical studies without evidence of clinical adverse interactions. These medications included thyroid hormones, sedative hypnotics, non-steroidal anti-inflammatory agents, benzodiazepines and decongestants. Phenobarbital, which induces hepatic metabolism, decreased the AUC of Montelukast approximately 40% following a single 10mg dose of Montelukast. No dosage adjustment for Montelukastis 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 overdosage 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. 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 : Store below 30°C in a dry place.

Packing : **M-Kast 4 ODT :** Each box contains 3x14's tablets in blister pack.

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M-Kast 10 : Each box contains 3x14's tablets in blister pack.