

Size : 120 x 170 mm

Montelukast Sodium

Kastorion

5 mg Chewable Tablet
10 mg Film-Coated Tablet
ANTIASTHMA

FORMULATION

Each chewable tablet contains:

Montelukast (as sodium) 5 mg

Each film-coated tablet contains:

Montelukast (as sodium).....10 mg

PHARMACOLOGY

Montelukast sodium is a selective, high affinity, competitive leukotriene receptor antagonist specifically the cysteinyl leukotriene (cyst-LT1) receptor. It suppresses both early and late bronchoconstrictor responses to inhaled antigens or irritants.

PHARMACOKINETICS

Peak plasma concentrations of Montelukast sodium are achieved in 2 to 4 hours after oral administration. The mean oral bioavailability is 64%. Montelukast sodium is more than 99% bound to plasma proteins. It is extensively metabolized in the liver by cytochrome P450 isoenzymes CYP3A4, CYP2A6, and CYP2C9, and is excreted principally in the faeces via the bile. The half-life of Montelukast sodium is between 3 to 6 hours. Metabolism was reduced and the elimination half-life prolonged in patients with mild to moderate hepatic impairment.

INDICATIONS

Montelukast sodium is used for the prophylaxis and chronic treatment of asthma, including the prevention of day and nighttime symptoms, treatment of aspirin-sensitive asthmatic patients, and prevention of exercise-induced bronchoconstriction; relief of symptoms of allergic rhinitis (seasonal and perennial allergic rhinitis) including nasal congestion, rhinorrhea, nasal itching, sneezing, nasal congestion upon awakening, difficulty going to sleep and nighttime awakenings; teary, itchy, and red puffy eyes.

CONTRAINDICATIONS

Patients with known hypersensitivity to the drug or any of its components.

WARNINGS/ PRECAUTIONS

Although a causal relationship with leukotriene receptor antagonism has not been established, caution and appropriate clinical monitoring are recommended when systemic corticosteroid reduction is considered in patients receiving Montelukast sodium.

Use in Pregnancy:

Montelukast sodium has not been studied in pregnant women. It should be used during pregnancy only if clearly needed.

Use in Lactation: It is not known if Montelukast sodium is excreted in human milk. Thus, caution should be exercised when Montelukast sodium is given to nursing mothers.

Use in Children:

Safety and effectiveness in pediatric patients <6 months have not been studied.

Use in Elderly:

There were no age-related differences in the efficacy or safety profiles of Montelukast sodium.

ADVERSE EVENTS

Adverse effects of Montelukast sodium includes edema, agitation and restlessness, allergy including anaphylaxis, angioedema, and urticaria, chest pain, tremor, dry mouth,

vertigo, and arthralgia. Further suspected adverse effects included nightmares, sedation, palpitations, and increased sweating. Churg-Strauss syndrome has been reported in association with Montelukast sodium. Although there is some evidence of effects on the liver in patients receiving Montelukast sodium, and although it is largely eliminated by hepatic metabolism, Montelukast sodium is not considered to be contraindicated in hepatic impairment, and no dose adjustment is considered necessary in mild to moderate hepatic impairment. No dosage adjustment is anticipated to be necessary in patients with renal impairment.

DRUG INTERACTIONS

It is recommended to have a clinical monitoring when potent hepatic enzyme inducers such as phenytoin, phenobarbital, or rifampicin are given with Montelukast sodium.

Montelukast sodium may inhibit the metabolism of drugs primarily metabolized by CYP2C8 (e.g. paclitaxel, repaglinide, and rosiglitazone).

DOSAGE AND ADMINISTRATION

Adults and Adolescents 15 years of age and older with Asthma and/or Allergic Rhinitis:

10 mg film-coated tablet once daily at bedtime.

Children aged 6-14 years:

5 mg chewable tablet at bedtime.

Children aged 2 to 5 years:

4 mg chewable tablet at bedtime.

For Chronic Asthma:

10 mg film-coated tablet once daily at bedtime.

For patients with Asthma and Seasonal Allergic Rhinitis:

5 mg chewable tablet in the evening once daily.

It should not be used to treat an acute asthma attack. Or as prescribed by the physician.

CAUTION: Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

STORE AT TEMPERATURES NOT EXCEEDING 30°C.

Keep in a cool dry place, protected from light.

AVAILABILITY

Montelukast Sodium 5 mg Chewable Tablet / blister pack x 5's (Box of 25's)

Montelukast Sodium 10 mg Film-coated Tablet / blister pack x 5's (Box of 25's)

Manufactured by:

Micro Labs Limited
92, SIPCOT Industrial Complex,
Hosur-635 126, Tamil Nadu, India

Imported by :

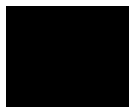
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