Montit™
(Montelukast)

Highnoon

COMPOSITION
Montit 5mg Chewable Tablet: Each chewable tablet contains: Montelukast (as Sodium) 5mg

Montit 10mg Tablet: Each film-coated tablet contains: Montelukast (as Sodium) 10mg

DESCRIPTION
Montelukast sodium the active ingredient in Montit, is a selective and orally active leukotriene receptor antagonist that inhibits the cysteinyl leukotriene CysLT1 receptor.

MECHANISM OF ACTION
The cysteinyl leukotrienes (LTC4, LTD4, LTE4) are products of arachidonic acid metabolism and are released from various cells, including mast cells and eosinophils. These eicosanoids bind to cysteinyl leukotriene (CysLT) receptors. The CysLT type-1 (CysLT1) receptor is found in the human airway (including airway smooth muscle cells and airway macrophages) and on other pro-inflammatory cells (including eosinophils and certain myeloid stem cells). Montelukast is an orally active compound that binds with high affinity and selectivity to the CysLT1 receptor (in preference to other pharmacologically important airway receptors, such as the prostanoid, cholinergic, or β-adrenergic receptor). Montelukast inhibits physiologic actions of LTD4 at the CysLT1 receptor without any agonist activity.

PHARMACOKINETICS
Peak plasma concentration of Montelukast occur 2 to 4 hours after oral dose. The mean oral bioavailability is about 64 to 73%. Montelukast is more than 99% bound to plasma proteins. It is extensively metabolized in the liver by cytochrome P450 isozymes, mainly by CYP2C8 and to a lesser extent by CYP3A4. The plasma-half-life ranges from 2.7 to 5.5 hours. Montelukast and its metabolites are excreted principally in the feces via the bile.

INDICATIONS AND USAGE
Asthma
It is indicated for the prophylaxis and chronic treatment of asthma in adults and pediatric patients 12 months of age and older.

Exercise-Induced Bronchoconstriction (EIB)
It is indicated for prevention of exercise-induced bronchoconstriction (EIB) in patients 6 years of age and older.

Allergic Rhinitis
It is indicated for the relief of symptoms of seasonal allergic rhinitis in patients 2 years of age and older and perennial allergic rhinitis in patients 6 months of age and older.

It is not indicated for the treatment of an acute asthma attack.

DOSAGE AND ADMINISTRATION
Asthma
- The dosage in adults and adolescents 15 years of age and older with asthma; is one 10 mg tablet daily to be taken in the evening.
- The dosage in patient 6 to 14 years of age; is one 5 mg chewable tablet daily to be taken in the evening.

Safety and effectiveness in pediatric patients less than 12 months of age with asthma have not been established.

Exercise-Induced Bronchoconstriction (EIB)
- The dosage in adults and adolescents 15 years of age and older with EIB; is one 10 mg tablet daily to be taken in the evening. For prevention of EIB, a single dose of 10 mg should be taken at least 2 hours before exercise.
- The dosage for patient 6 to 14 years of age; is one 5 mg chewable tablet daily to be taken in the evening.
- An additional dose should not be taken within 24 hours of a previous dose. Patients already taking Montelukast daily for another indication (including chronic asthma) should not take an additional dose to prevent EIB. All patients should have available for rescue a short-acting β-agonist.
- Safety and efficacy in patients younger than 6 years of age have not been established. Daily administration of Montelukast for the chronic treatment of asthma has not been established to prevent acute episodes of EIB.

Allergic Rhinitis
- The dosage for adults and adolescents 15 years of age and older; is one 10 mg tablet daily to be taken in the evening, without regard to time of food ingestion.
- The dosage for patient 6 to 14 years of age; is one 5 mg chewable tablet daily to be taken in the evening. Safety and effectiveness in pediatric patients younger than 2 years of age with seasonal allergic rhinitis have not been established.

Perennial allergic rhinitis
- The dosage for adults and adolescents 15 years of age and older is one 10 mg tablet daily to be taken in the evening, without regard to time of food ingestion.
- The dosage for patient 6 to 14 years of age; is one 5 mg chewable tablet daily to be taken in the evening.
- Safety and effectiveness in pediatric patients younger than 6 months of age with perennial allergic rhinitis have not been established.

CONTRAINDICATIONS
- Hypersensitivity to any component of this product.

WARNINGS AND PRECAUTIONS
- It is not indicated for use in the reversal of Broncho-spasm in acute asthma attacks, including status asthmaticus. Patients should be advised to have appropriate rescue medication available. Patients who have exacerbations of asthma after exercise should have available for rescue a short-acting inhaled β-agonist. Patients should seek their doctor's advice as soon as possible if they need more inhalations of short-acting β-agonists than usual.
- While the dose of inhaled corticosteroid may be reduced gradually under medical supervision. Montelukast should not be abruptly substituted for inhaled or oral corticosteroids.
- Treatment with montelukast does not alter the need for patients with aspirin-sensitive asthma to avoid taking aspirin and other non-steroidal anti-inflammatory drugs.
- Serious neuropsychiatric (NP) events have been reported with use of montelukast. These included, but were not limited to, agitation, aggressive behavior or hostility, anxiousness, depression, disorientation, disturbance in attention, dream abnormalities, dysphemia (stuttering), hallucinations, insomnia, irritability, memory impairment, obsessive-compulsive symptoms, restlessness, somnambulism, suicidal thoughts and behavior (including suicide), tic, and tremor. NP events have been reported in adult, adolescent, and pediatric patients with and without a previous history of psychiatric disorder. Because of the risk of NP events, the benefits of montelukast may not outweigh the risks in some patients, particularly when the symptoms of disease may be mild and adequately treated with alternative therapies. Reserve use of montelukast for patients with allergic rhinitis who have an inadequate response or intolerance to alternative therapies. In patients with asthma or exercise-induced bronchoconstriction, consider the benefits and risks before prescribing montelukast. Discuss the benefits and risks of montelukast use with patients and caregivers when prescribing montelukast. If changes in behavior are observed, or if new NP symptoms or suicidal thoughts and/or behavior occur, advise patients to discontinue montelukast and contact a healthcare provider immediately. In many cases, symptoms resolved after stopping montelukast therapy; however, in some cases symptoms persisted after discontinuation of montelukast. Therefore, continue to monitor and provide supportive care until symptoms resolve.
- Patients with asthma on therapy with Montelulast may present with systemic eosinophilia, sometimes presenting with clinical features of vasculitis consistent with Churg-Strauss syndrome, a condition which is often treated with systemic corticosteroid therapy. These events have been sometimes associated with the reduction of oral corticosteroid therapy. Physicians should be alert to eosinophilia, vasculitic rash, worsening pulmonary symptoms, cardiac complications, and/or neuropathy presenting in their patients. A causal association between Montelukast and these underlying conditions has not been established.
- Chewable tablet contains aspartame; it may be harmful for children with phenylketonuria.

ADVERSE REACTIONS
The common reported adverse events of montelukast are upper respiratory infection, fever, headache, pharyngitis, laryngitis, cough, abdominal pain, diarrhea, otitis media, influenza, rhinorrhea, sinusitis, otitis, abdominal pain, asthenia, fatigue, trauma, dyspepsia, dental pain. gastroenteritis, dizziness, nasal congestion, rash, ALT increased, AST increased, pyuria, viral infection, varicella, atopic dermatitis, acute bronchitis, tooth infection, skin infection, eczema, urticaria, dermatitis, conjunctivitis, myopia, ear pain, pneumonia, wheezing, tonsillitis, otitis media, epistaxis, somnolence, agitation, aggressive behavior or hostility, anxiousness, depression, disorientation, disturbance in attention, dream abnormalities, dysphemia (stuttering), hallucinations, insomnia, irritability, memory impairment, obsessive-compulsive symptoms, restlessness, somnambulism, suicidal thoughts and behavior (including suicide), tic, and tremor.
The additional reported adverse events are increased bleeding tendency, thrombocytopenia, hypersensitivity reactions including anaphylaxis, hepatic eosinophilic infiltration, drowsiness, paresthesia, hypoesthesia, seizures, palpitations, pulmonary eosinophilia, nausea, pancreatitis, vomiting, cases of cholestatic hepatitis, hepatocellular liver-injury, mixed-pattern liver injury, angioedema, bruising, erythema multiforme, erythema nodosum, pruritus, Stevens-Johnson syndrome/toxic epidermal necrolysis, arthralgia, myalgia including muscle cramps, enuresis in children, edema, vasculitis rash, Churg-Strauss syndrome, eosinophilia, worsening pulmonary symptoms, porphyria, akathisia, anxiety, sleep disorder, sensation abnormal and cardiac complications.

DRUG INTERACTIONS
Montelukast may be administered with other therapies routinely used in the prophylaxis and chronic treatment of asthma. No dose adjustment is needed when Montelukast is co-administered with theophylline, prednisone, prednisolone, oral contraceptives, terfenadine, digoxin, warfarin, gemfibrozil, litraconazole, thyroid hormones, sedative hypnotics, non-steroidal anti-inflammatory agents, benzodiazepines, decongestants, and Cytochrome P450 (CYP) enzyme inducers.

USE IN SPECIFIC POPULATIONS
Pregnancy
Published data have not identified an association with Montelukast use during pregnancy and major birth defects.

Lactation
Studies in rats have shown that montelukast is excreted in milk. The effects of the drug on milk production are unknown. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for montelukast and any potential adverse effects on the breastfed infant from montelukast or from the underlying maternal condition.

Pediatric Use
Please see dosage and administration section.

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

Hepatic Impairment
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.

OVERDOSAGE
No specific information is available on the treatment of overdose with montelukast

DOSAGE AND INSTRUCTIONS
To be sold and used on the prescription of a registered medical practitioner only. Keep out of reach of children. Do not store above 30°C. Keep in a dry place. Protect from light.

PRESENTATION
Montit 5mg Tablets: Alu. Alu. Blister Pack of 2 x 7's.
Montit 10mg Tablets: Alu. Alu. Blister Pack of 2 x 7's.

مونٹیٹ™
(مونٹیلوکاسٹ)

خوراک و ہدایات:
صرف مستند ڈاکٹر کے نسخہ کے مطابق ہی دوا فروخت اور استعمال کی جائے۔
بچوں کی پہنچ سے دور رکھیں۔ 30°C سے زیادہ درجہ حرارت پر نہ رکھیں۔
خشک جگہ پر رکھیں۔ روشنی سے بچائیں۔

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Marketed by
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