Natrapharm

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Montelukast sodium

Montemax®

4mg Chewable tablet
5mg Chewable tablet
10mg Film coated tablet
Leukotriene Receptor Antagonist

FORMULATION:
Each chewable tablet contains:
Montelukast (as sodium) 4.2mg
(equivalent to 4mg montelukast)
Montelukast (as sodium) 5.2mg
(equivalent to 5mg montelukast)
Each film-coated tablet contains:
Montelukast (as sodium) 10.4mg
(equivalent to 10mg montelukast)

INDICATIONS:
Montelukast (Montemax) is indicated for the prophylaxis and chronic treatment of asthma in adults and pediatric patients 12 months of age or older.

Montelukast (Montemax) is indicated for the relief of symptoms of allergic rhinitis (seasonal allergic rhinitis in adults and pediatric patients 2 years of age and older) and perennial allergic rhinitis in adults and pediatric patients in 6 months of age and older.

DOSAGE AND ADMINISTRATION:
Montelukast (Montemax) 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 patient needs. Patients with both asthma and allergic rhinitis should take only one tablet daily in the evening.
Adults and 15 years and older with asthma and allergic rhinitis: 10mg tablet daily.
Patients below 15 years old with asthma and allergic rhinitis: one 5mg chewable tablet daily. No dosage adjustment within this age group is necessary.
Children between 2 to 5 years old with asthma and allergic rhinitis: One 4mg chewable tablet daily.

PHARMACODYNAMICS
Montelukast is an orally active compound which binds with high affinity and selectivity to the $CysLT_1$ receptor.

The cysteinyl leukotrienes [CysLT (LTC_4, LTD_4, and LTE_4)] are potent inflammatory eicosanoids released from various cells including mast cells and eosinophils that bind to CysLT receptors. The CysLT type1 ($CysLT_1$) receptor is present in the human airway (including airway smooth muscle cells and airway macrophages). CysLTs contribute to the pathophysiology of asthma and allergic rhinitis. In asthma, CysLTs are found to increase mucus secretion, vascular permeability, and bronchoconstriction. In allergic rhinitis, CysLTs are released from the nasal mucosa after exposure to allergens and are associated with symptoms of allergic rhinitis. Montelukast inhibits bronchoconstriction and reduces inflammation of the nasal mucosa induced by exposure to known precipitants.

PHARMACOKINETICS:
Montelukast is a selective and orally active leukotriene receptor antagonist that specifically inhibits the cysteinyl leukotriene $CysLT_1$-receptor.

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

WARNINGS AND PRECAUTIONS:
Neuropsychiatric events have been reported in patients taking montelukast (see **ADVERSE REACTIONS**). Patients should inform their physician if these changes occur.

Eosinophilia, vasculitic rash, worsening pulmonary symptoms, cardiac complications, and/or neuropathy sometimes diagnosed as Churg-Strauss syndrome have been reported rarely in patients with asthma being treated with montelukast.

USE IN PREGNANCY AND LACTATION:
There is no adequate and well-controlled studies in pregnant women, therefore, 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.

USE IN ELDERLY:
No overall differences in safety or efficacy were observed between the elderly and the younger persons, but greater sensitivity of some other individuals cannot be ruled out.

ADVERSE EFFECT:
Edema, agitation and restlessness, allergy including anaphylaxis, angioedema and urticaria, chest pain, tremor, dry mouth, vertigo and arthralgia.

Post Marketing Experience: The following additional adverse reactions have been reported in post-marketing use:
Infections and Infestations: upper respiratory infection
Blood and Lymphatic system disorders: increased bleeding tendency
Immune system disorders: hypersensitivity, reactions including anaphylaxis, very rarely hepatic eosinophilic infiltration
Psychiatric disorders: agitation including aggressive behavior or hostility, anxiousness, depression, disorientation, disturbance in attention, dream abnormalities, hallucinations, insomnia, memory impairment, psychomotor hyperactivity (including irritability, restlessness, and tremor) somnambulism, suicidal thinking and behavior (suicidality).
Nervous system disorders: dizziness, drowsiness, paresthesia/hypoesthesia, very rarely seizures
Cardiac disorders: palpitations
Respiratory, thoracic and mediastinial disorders: epistaxis
Gastrointestinal disorders: diarrhea, dyspepsia, nausea, vomiting
Hepatobiliary disorders: increased ALT and AST, very rarely hepatitis (including cholestatic, hepatocellular, and mixed-pattern liver injury)
Skin and subcutaneous tissue disorders: angioedema, bruising, erythema multiforme, erythema nodosum, pruritus, rash, urticarial
Muskoloskeletal and connective tissue disorders: arthralgia, myalgia including muscle cramps.
General disorders and administration site conditions: asthenia/fatigue, edema, pyrexia

DRUG INTERACTIONS:
Clinical monitoring when montelukast is administered with a potent hepatic enzyme inducers such as phenytoin, phenobarbital or rifampicin.

CONTRAINDICATIONS:
Hypersensitivity to any component of Montemax.

OVERDOSAGE:
No specific information is available on the treatment of overdosage with montelukast. In chronic asthma studies, montelukast has been administered at doses up to 200mg/day to patients for 22 weeks and in short-term studies, up to 900mg/day to patients for approximately 1 week without clinically important adverse experiences. There have been reports of acute overdosage in children in post-marketing experience and clinical studies of up to at least 150mg/day with montelukast. The clinical and laboratory findings observed were consistent with the safety profile in adults and older pediatric patients. There were no adverse experiences reported in the majority of overdosage reports. The most frequent adverse experiences observed were thirst, somnolence, mydriasis, hyperkinesia and abdominal pain. It is not known whether montelukast is dialyzable by peritoneal- or hemodialysis.

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

For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph

AVAILABILITY:
Alu-Alu Blister pack x 10's (Box of 30's) ; Alu-Alu Blister pack x 15's (Box of 15's)

Registration Number:
4mg chewable tablet (DR-XY32840), 5mg chewable tablet (DR-XY32839),
10mg film-coated tablet (DR-XY32707)

Date of First Authorization: January 2007; December 2006

Revision Date: July 2023

STORE AT TEMPERATURES NOT EXCEEDING 30°C
PROTECT FROM MOISTURE AND LIGHT
KEEP OUT OF REACH OF CHILDREN

Manufactured by
Lloyd Laboratories, Inc.
No. 10 Lloyd Ave.,
First Bulacan Industrial City,
City of Malolos, Bulacan
Manufactured For
Natrapharm, Inc.
The Patriot Building
Km 18 West Service Road,
SLEX, Sucat, Parañaque City

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