Size : 165x120 mm

Montelukast Sodium + Levocetirizine Dihydrochloride

Monti Plus

10mg / 5mg Tablet

Leukotriene Receptor Antagonist

Rx

FORMULATION:

Each uncoated tablet contains:

Montelukast Sodium

Eq. to Montelukast ..... 10 mg

Levocetirizine Dihydrochloride ..... 5 mg

PHARMACOLOGY:

As Montelukast Sodium + Levocetirizine Hydrochloride is a combination of Montelukast and Levocetirizine; the pharmacological properties of both the molecules are given separately:

Montelukast sodium is a selective and orally active leukotriene receptor antagonist that inhibits the cysteinyl leukotriene (CysLT1), receptor.

Levocetirizine is the R-enantiomer of cetirizine. Levocetirizine is an orally active, potent, selective and long acting H1 -histamine receptor antagonist with no anticholinergic activity.

Studies have demonstrated that Allergic Rhinitis [AR] when treated concomitantly with an antileukotriene (Montelukast) and an antihistamine (Levocetirizine), shows significantly better symptom relief compared with the modest improvement of rhinitis symptoms with each of the treatments alone.

PHARMACOKINETICS:

Peak plasma concentrations of Montelukast are achieved in 3 to 4 hours after oral doses. The mean oral bioavailability is 64%. Montelukast is more than 99% bound to plasma proteins. It is extensively metabolised in the liver by cytochrome P450 isoenzymes CYP3A4, CYP2A6, and CYP2C9, and is excreted principally in the faeces via the bile.

Levocetirizine is rapidly absorbed from the gastrointestinal tract after oral doses, peak plasma concentrations being attained within about an hour. Food delays the time to peak plasma concentrations but does not decrease the amount of drug absorbed. Levocetirizine is highly bound to plasma proteins and has an elimination half-life of about 10 hours. It has been detected in breast milk. Levocetirizine is excreted primarily in the urine mainly as unchanged drug. It does not appear to cross the blood-brain barrier to a significant extent.

INDICATION:

Montelukast Sodium + Levocetirizine Hydrochloride Tablets are indicated for relief of symptoms of allergic rhinitis [seasonal or perennial], as prophylaxis in seasonal allergic rhinitis and treatment of comorbid asthma and allergic rhinitis in patients 15 years of age and over.

DOSAGE AND ADMINISTRATION:

One Montelukast Sodium + Levocetirizine Hydrochloride Tablet once daily.

Or as directed by the physician.

CONTRAINDICATIONS:

Montelukast Sodium + Levocetirizine Hydrochloride is contraindicated in patients with known hypersensitivity to Montelukast sodium, Levocetirizine or to any other component of this product. It is also contraindicated in patients with severe renal impairment at less than 10 mL/min creatinine clearance.

PRECAUTIONS:

Patients should be advised never to use oral Montelukast to treat acute asthma attacks and to keep their usual appropriate rescue medication for this purpose readily available. If an acute attack occurs, a short-acting inhaled β-agonist should be used. Patients should seek their doctors' advice as soon as possible if they need more inhalations of short-acting β-agonists than usual. Montelukast should not be substituted for inhaled or oral corticosteroids. Although drowsiness is rare, it can occur and may affect the performance of skilled tasks. Occasional reports of convulsions in patients taking antihistamines suggest a need for caution in patients with epilepsy. Many antihistamines are excreted in the urine in the form of active metabolites so that dosage reduction may be necessary in renal impairment. As for the non-sedating antihistamines in general, reduced dosage is recommended for patients with hepatic or renal impairment.

Pregnancy:
There are no adequate and well-controlled studies of either Montelukast or levocetirizine in pregnant women. Hence, this combination should not be used during pregnancy.

Lactation:
Since levocetirizine is excreted in breast-milk so the combination is not recommended during lactation.

ADVERSE EFFECTS:
The most common side effects with Montelukast are headache, dizziness, abdominal pain, sore throat, and rhinitis (inflammation of the inner lining of the nose).

DRUG INTERACTION:
Montelukast: Phenobarbital increases the blood concentration of Montelukast by about 40%. Rifampin may have the same effect. Therefore, the dose of Montelukast may need to be reduced when given concurrently with these drugs.
Levocetirizine: some interactions are less likely with cetirizine than with non-sedating antihistamines such as astemizole and terfenadine, since cetirizine appears to have low hepatic metabolism and little arrhythmogenic potential.

OVERDOSAGE AND TREATMENT:
Overdosage has been reported with Levocetirizine dihydrochloride.
Symptoms of overdose may include drowsiness in adults and initially agitation and restlessness, followed by drowsiness in children. There is no known specific antidote to Levocetirizine dihydrochloride. Should overdose occur, symptomatic or supportive treatment is recommended. Levocetirizine dihydrochloride is not effectively removed by dialysis, and dialysis will be ineffective unless a dialyzable agent has been concomitantly ingested.
The acute maximal non-lethal oral dose of Levocetirizine was 240 mg/kg in mice (approximately 190 times the maximum recommended daily oral dose in adults, approximately 230 times the maximum recommended daily oral dose in children 6 to 11 years of age, and approximately 180 times the maximum recommended daily oral dose in children 6 months to 5 years of age on a mg/m2 basis). In rats the maximal non-lethal oral dose was 240 mg/kg (approximately 390 times the maximum recommended daily oral dose in adults, approximately 460 times the maximum recommended daily oral dose in children 6 to 11 years of age, and approximately 370 times the maximum recommended daily oral dose in children 6 months to 5 years of age on a mg/m2 basis).

No specific information is available on the treatment of overdosage with Montelukast. In chronic asthma studies, Montelukast has been administered at doses up to 200 mg/day to adult patients for 22 weeks and, in short-term studies, up to 900 mg/day to patients for approximately a week without clinically important adverse experiences. 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.
There have been reports of acute overdosage in post-marketing experience and clinical studies with Montelukast. These include reports in adults and children with a dose as high as 1000 mg. The clinical and laboratory findings observed were consistent with the safety profile in adults and pediatric patients. 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.
It is not known whether Montelukast is removed by peritoneal dialysis or hemodialysis.

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

STORAGE CONDITION:
Store at temperatures not exceeding 30°C.
Keep all medicines out of children's reach.

AVAILABILITY:
Alu /Alu blister pack 10's (Box of 30's).

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