MONTELUKAST

PEDIAIR

4 mg Granules
Leukotriene Receptor Antagonist

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FORMULATION:
Each sachet (1 g) contains :
Montelukast Sodium
Eq. to Montelukast.....4 mg

PRODUCT DESCRIPTION:
White to off-white granular powder that yields an odourless white to off-white suspension on reconstitution with water.

PHARMACOLOGY:
Montelukast is a leukotriene receptor antagonist (LTRA) used for the maintenance treatment of asthma and to relieve symptoms of seasonal allergies. It is usually administered orally. Montelukast is a CysLT1 antagonist; that blocks the action of leukotriene D4 on the cysteinyl leukotriene receptor CysLT1 in the lungs and bronchial tubes by binding to it. This reduces the bronchoconstriction otherwise caused by the leukotriene, and results in less inflammation.

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.

INDICATIONS:
In the management of chronic asthma, allergic rhinitis, and as prophylaxis for exercise-induced asthma.

DOSAGE AND ADMINISTRATION:
One sachet of Montelukast 4 mg granules to be taken in evening time.
Or as prescribed by the physician.

DIRECTION FOR USE:
Empty sachet contents into a small cup containing 2 tablespoons of water. Do not use other liquids or food. Stir well and drink immediately. Re-fill cup with water and drink.

CONTRAINDICATION:
Known hypersensitivity to the active substance or to any of the excipients.

SPECIAL WARNINGS AND PRECAUTIONS FOR USE:
Contraindicated in hepatic impairment and no dose adjustment is considered necessary in mild to moderate hepatic impairment.

The diagnosis of persistent asthma in very young children (6 months – 2 years) should be established by a paediatrician or pulmonologist.
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 beta-agonist should be used. Patients should seek their doctors' advice as soon as possible if they need more inhalations of short-acting beta-agonists than usual.

Montelukast should not be abruptly substituted for inhaled or oral corticosteroids.

There are no data demonstrating that oral corticosteroids can be reduced when montelukast is given concomitantly.
In rare cases, patients on therapy with anti-asthma agents including montelukast 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 cases usually, but not always, have been associated with the reduction or withdrawal of oral corticosteroid therapy. The possibility that leukotriene receptor antagonists may be associated with emergence of Churg-Strauss syndrome can neither be excluded nor established. Physicians should be alert to eosinophilia, vasculitic rash, worsening pulmonary symptoms, cardiac complications, and/or neuropathy presenting in their patients. Patients who develop these symptoms should be reassessed and their treatment regimens evaluated.

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.

Pregnancy:
Montelukast may be used during pregnancy only if it is considered to be clearly essential.

Lactation:
Montelukast is excreted in milk. It is not known if Montelukast is excreted in human milk. Montelukast may be used in breastfeeding only if it is considered to be clearly essential.

ADVERSE DRUG REACTIONS:
Adverse drug reactions of montelukast included the following:
CNS: vertigo
Neuropsychiatric: agitation, nightmares, restlessness, and sedation
Cardiovascular: Palpitations, chest pain
Subcutaneous/Skin: angioedema, urticaria, edema
Musculoskeletal: arthralgia, tremors
Further suspected adverse effects included increased sweating, dry mouth, and allergy (i.e. anaphylaxis)

DRUG INTERACTION:
Caution recommends when potent inducers of the cytochrome P450 isoenzyme CYP3A4 such as phenytoin, phenobarbital, or rifampicin are given with Montelukast.

OVERDOSE AND TREATMENT:
No specific information is available on the treatment of overdose 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 one week without clinically important adverse experiences.

There have been reports of acute overdose in post-marketing experience and clinical studies with Montelukast. These include reports in adults and children with a dose as high as 1,000 mg (approximately 61 mg/kg in a 42 month old child). The clinical and laboratory findings observed were consistent with the safety profile in adults and paediatric patients. There were no adverse experiences in the majority of overdose 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 dialyzable by peritoneal- or hemo dialysis.

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

For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph.
Seek medical attention immediately at the first sign of any adverse drug reaction.

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

AVAILABILITY:
Aluminum Sachet (Box of 20's).

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