Maxair ™
Montelukast

Composition:
Maxair ™ 5 Tablet: Each chewable tablet contains Montelukast Sodium USP equivalent to Montelukast 5 mg.
Maxair ™ 10 Tablet: Each film coated tablet contains Montelukast Sodium USP equivalent to Montelukast 10 mg.

Pharmacology:
Montelukast is a selective and orally active leukotriene receptor antagonist that inhibits the cysteinyl leukotriene CysLT receptor. Cysteinyl leukotrienes and leukotriene receptor occupation have been correlated with the pathophysiology of asthma (such as, airway edema, smooth muscle contraction and altered cellular activity associated with the inflammatory process contribute to the signs and symptoms of asthma).

Indications:
Maxair ™ is indicated for the prophylaxis and chronic treatment of asthma in adults and paediatric patients 6 years of age and older. **Maxair ™** is indicated for the relief of symptoms of seasonal allergic rhinitis in adults and paediatric patients 2 years of age and older.

Dosage and administration:
Children (6-14 years of age): 5 mg daily to be taken in the evening. **Maxair ™** 5 should be taken one hour before or 2 hours after food. No dosages adjustment within this age group is necessary.

Adults (15 years of age or over): 10 mg daily to be taken in the evening.

OR AS DIRECTED BY THE PHYSICIAN.

Contra-indication:
Montelukast is contraindicated to patients with hypersensitivity to any component of this product.

Waning & precautions:
Montelukast is not indicated for use in the reversal bronchospasm in acute asthma attacks, including status asthmaticus. Montelukast should not be abruptly substituted for inhaled or oral corticosteroids. Montelukast should not be use monotherapy for the treatment and management of exercise induced bronchospasm. Patients with known aspirin sensitivity should continue avoidance of aspirin or non-steroidal anti-inflammatory agents while taking Montelukast. Although Montelukast is effective in improving airway function in asthmatics with documented aspirin sensitivity, it has not been shown truncate bronchoconstrictor response to aspirin and

other non steroidal anti-inflammatory drugs in aspirin-sensitive asthmatic patients.

Side effects:
Generally, Montelukast is well-tolerated. Side effects include dizziness, headache, diarrhea, restlessness, abdominal pain, cough, fever, asthenia, rash and upper respiratory tract infection.

Use in pregnancy & lactation:
Pregnancy: There are no adequate and well-controlled studies of Montelukast in pregnant women. Montelukast should be used during pregnancy only if clearly needed.

Lactation: It is not known if Montelukast is excreted in human milk. Because many drugs are excreted in human milk, so caution should be exercised when Montelukast is given to a nursing mother.

Drug interactions:
Montelukast may be administered with other therapies routinely used in the prophylaxis and chronic treatment of asthma. In drug-interactions studies, the recommended clinical dose of montelukast did not have clinically important effects on the pharmacokinetics of the following medicinal products: theophylline, prednisolone, oral contraceptives (norethindrone 1 mg / ethinyl estradiol 35 mcg), terfenadine, digoxin and warfarin. Since montelukast is metabolised by CYP 3A4, caution should be exercised, particularly in children, when montelukast is co-administered with inducers of CYP 3A4, such as phenytoin, phenobarbital and rifampicin.

Over dose:
There were no adverse experiences reported in the majority of overdosage reports. The most frequent adverse experiences observed were thirst, mydriasis, hyperkinesias and abdominal pain. 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.

Storage:
Keep out of the reach of children. Store in a cool and dry place below 30^{0}C, protect from light.

Packing:
Maxair ™ **5 Tablet:** Each box contains 30 tablets in blister packs.
Maxair ™ **10 Tablet:** Each box contains 20 tablets in blister packs.

Manufactured by:

Jenphar Bangladesh Ltd.
Sreepur, Gazipur, Bangladesh.

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