

# Airway

## Montelukast

### Composition

**Airway 4 mg Tablet:** Each oroflash tablet contains Montelukast Sodium BP equivalent to Montelukast 4 mg.

**Airway 5 mg Tablet:** Each film coated tablet contains Montelukast Sodium BP equivalent to Montelukast 5 mg.

**Airway 10 mg Tablet:** Each film coated tablet contains Montelukast Sodium BP equivalent to Montelukast 10 mg.

### Pharmacology

Montelukast is a selective and orally active leukotriene receptor antagonist that inhibits the cysteinyl leukotriene CysLT1 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, which contribute to the signs and symptoms of asthma).

### Indication

Montelukast is indicated for the prophylaxis and chronic treatment of asthma in adults and pediatric patients.

### Dose and Administration

a) *Route of administration:* Oral

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

Children (6-14 years of age): 5 mg daily to be taken in the evening.

Children (6 months to 5 years of age): 4 mg oroflash tablet daily to be taken in the evening.

The safety and efficacy of Montelukast was demonstrated in clinical trials where it was administered in the evening without regard to the time of food ingestion.

### Contra-indication

Montelukast is contraindicated to patients with hypersensitivity to any component of this product.

### Warning & Precautions

Montelukast is not indicated for use in the reversal of bronchospasm in acute asthma attacks (in case of status asthmaticus). Patients with known aspirin sensitivity should continue avoidance of aspirin or other NSAID, while taking Montelukast. In rare cases, patients on therapy with 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. Physician 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.

### Side effect

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

b) *Rare:* No adequate data are available.

### Pregnancy and lactation

*Pregnancy:* There are no adequate and well-controlled studies of Montelukast in pregnant women. Because animal reproductive studies are not always predictive of human response, so 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.

### Use in Children & Adolescents

Should be used as per direction of physician.

### Drug interaction

a) *With Medicine:* Montelukast has been administered with other therapies routinely used in the prophylaxis and chronic treatment of asthma with no appropriate increase in adverse reactions. Cytochrome P-450 inducers: Although Phenobarbital induces hepatic metabolism, no dosage adjustment for Montelukast is recommended. It is reasonable to employ appropriate clinical monitoring when potent cytochrome P-450 enzyme inducers, such as Phenobarbital or Rifampin, are co-administered with Montelukast.

b) *With food & others:* No adequate data are available.

### Overdose

There were no adverse experiences reported in the majority of overdose reports. The most frequent adverse experiences observed were thirst, mydriasis, hyperkinesia, 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

Store below 30°C. Protect from light and moisture. Keep all medicines out of reach of children.

### Packing

**Airway 4 mg Tablet:** Each box contains 30 (3x10's) Tablets in Alu-Alu Blister Pack.

**Airway 5 mg Tablet:** Each box contains 20 (2x10's) Tablets in Alu-Alu Blister Pack.

**Airway 10 mg Tablet:** Each box contains 30 (3x10's) Tablets in Alu-Alu Blister Pack.

Manufactured by  
**ONE PHARMA LTD.**  
C-23-24, BSCIC I/A  
Bogura, Bangladesh



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