

**Composition:**

Montril-4 Tablet: Each oroflash tablet contains Montelukast Sodium USP 4.150 mg equivalent to Montelukast 4 mg.

Montril-5 Tablet: Each chewable tablet contains Montelukast Sodium USP 5.190 mg equivalent to Montelukast 5 mg.

Montril-10 Tablet: Each film coated tablet contains Montelukast Sodium USP 10.380 mg 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.

Indications:

Montelukast is indicated for

- The prophylaxis and treatment of chronic asthma
- Relief of symptoms of Seasonal Allergic Rhinitis (SAR) and Perennial Allergic Rhinitis (PAR)
- Prevention of Exercise-Induced Bronchoconstriction (EIB)

Dosage & Administration:

One Tablet should be taken in the evening as per the following instruction-

- Children 6 months to 5 years: 4 mg oroflash tablet.
- Children 6 to 14 years: 5 mg chewable tablet.
- 15 years & Older: 10 mg tablet.

Acute Prevention of EIB: One tablet at least 2 hours before exercise for patients 6 years of age & older.

Contraindications:

Contraindicated to patients with hypersensitivity to Montelukast.

Side effects:

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

Precautions:

Serious neuropsychiatric events (e.g. agitation, aggression, depression, sleep disturbances, suicidal thoughts and behavior, etc.) have been reported with the use of Montelukast. Because the benefits of Montelukast may not outweigh the risk of neuropsychiatric symptoms in patients with allergic rhinitis. Hence, it is recommended that reserve use of Montelukast for patients with allergic rhinitis who have an inadequate response or intolerance to alternative therapies. Montelukast should not be used in the reversal of bronchospasm in acute asthma attacks. Patients with known aspirin sensitivity should avoid aspirin or other NSAIDs, 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.

Use in pregnancy and lactation:

In pregnancy: Pregnancy category B drug. There are no adequate and well-controlled studies in pregnant women. Montelukast should be used during pregnancy only if clearly needed.

In lactation: It is not known if Montelukast is excreted in human milk. Caution should be exercised when Montelukast is given to nursing mother.

Drug interactions:

Montelukast has been administered with other therapies routinely used in the prophylaxis and chronic treatment of asthma.

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.

Overdosage:

There were no adverse experiences reported in the majority of overdosage reports.

In the event of overdose, it is reasonable to employ the usual supportive measures.

Storage:

- **Montril-4 & Montril-5 Tablet:** Store below 25°C, keep in dry place & protect from light.
- **Montril-10 Tablet:** Store below 30°C, keep in dry place & protect from light.
- Keep out of the reach of children.

Packing:

Montril-4 Tablet: Each box contains 30's tablets in blister pack.

Montril-5 Tablet: Each box contains 30's tablets in blister pack.

Montril-10 Tablet: Each box contains 30's tablets in blister pack.

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Manufactured by:

 **ARISTOPHARMA LTD.**
Shampur-Kadamtali I/A, Dhaka-Bangladesh