# Montene™

## Montelukast

**COMPOSITION**
**Montene™ 4** Tablet: Each chewable tablet contains Montelukast Sodium USP equivalent to Montelukast 4 mg.
**Montene™ 5** Tablet: Each chewable tablet contains Montelukast Sodium USP equivalent to Montelukast 5 mg.
**Montene™ 10** Tablet: Each film-coated tablet contains Montelukast Sodium USP equivalent to Montelukast 10 mg.

**PHARMACOLOGY**
The cysteinyl leukotrienes ($LTC_4$, $LTD_4$, $LTE_4$) are products of arachidonic acid metabolism and are released from various cells, including mast cells and eosinophils. These eicosanoids bind to cysteinyl leukotriene receptors (CysLT) found in the human airway.
Montelukast is an orally active compound that binds with high affinity and selectivity to the $CysLT_1$ receptor. Montelukast inhibits physiologic actions of $LTD_4$ at the $CysLT_1$ receptor without any agonist activity.

**INDICATION**
Montelukast is a leukotriene receptor antagonist indicated for:
• Prophylaxis and chronic treatment of asthma in patients 12 months of age and older.
• Acute prevention of Exercise-Induced Bronchoconstriction (EIB) in patients 6 years of age and older.
• Relief of symptoms of Allergic Rhinitis (AR): Seasonal Allergic Rhinitis (SAR) in patients 2 years of age and older, and perennial allergic rhinitis (PAR) in patients 6 months of age and older.

**DOSAGE & ADMINISTRATION**
*By indications*
• Asthma: Once daily in the evening for patients 12 months and older.
• Acute prevention of EIB: One tablet at least 2 hours before exercise for patients 6 years of age and older.
• Seasonal Allergic Rhinitis: Once daily for patients 2 years and older.
• Perennial Allergic Rhinitis: Once daily for patients 6 months and older.
*By age*
• 15 years and older: One 10-mg tablet.
• 6 to 14 years: One 5-mg chewable tablet.
• 2 to 5 years: One 4-mg chewable tablet.

**CONTRA-INDICATION**
Hypersensitivity to any component of this product.

**ADVERSE EFFECT**
Montelukast appears to be well tolerated. In clinical trials, the most common adverse effect reported was headache, occurring in approximately 18% of patients. Rash, dyspepsia, dizziness, and abdominal pain were all reported in less than 2% of patients. Elevated liver transaminases have been reported with montelukast use, but not at a greater incidence than with placebo. A small percentage of pediatric patients have experienced diarrhea, sinusitis and otitis media during montelukast clinical trials.

**PRECAUTION**
Montelukast is not indicated for use in the reversal of bronchospasm in acute asthma attacks, including status asthmaticus. Patients should be advised to have appropriate rescue medication available.

**DRUG INTERACTION**
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 following medicinal products: theophylline, prednisone, prednisolone, oral contraceptives, terfenadine, digoxin and warfarin.
Caution should be exercised, particularly in children, when montelukast is co-administered with phenytoin, phenobarbital and rifampicin.

**USE IN PREGNANCY AND LACTATION**
Montelukast is classified as pregnancy category B. The drug has been shown to cross the placenta of pregnant rats and rabbits, but there have been no reports of its use in pregnant women. Montelukast is also known to be excreted into breast-milk, but only limited information is available on the significance of this finding. Caution should be used prior to initiating montelukast therapy in nursing mothers.

**STORAGE CONDITION**
Store below $25^0$ C at a cool and dry place, away from light and moisture. Keep out of reach of children.

**HOW SUPPLIED**
**Montene™ 4** tablet: Box containing 20 tablets in Alu-Alu blister pack.
**Montene™ 5** tablet: Box containing 20 tablets in Alu-Alu blister pack.
**Montene™ 10** tablet: Box containing 20 tablets in Alu-Alu blister pack.

*Manufactured by*
**SQUARE**
**PHARMACEUTICALS LTD.**
Kaliakoir, Bangladesh