

# **MONTEX**

## **MONTELUKAST BP**

### **Compositions:**

Montex 5 tablet: Each chewable tablet contains 5.2 mg Montelukast Sodium INN equivalent to 5 mg Montelukast. Montex 10 tablet: Each film coated tablet contains 10.4 mg Montelukast Sodium INN equivalent to 10 mg Montelukast.

### **Pharmacology:**

Montex (Montelukast sodium) is a selective and orally active leukotriene receptor antagonist that inhibits the cysteinyl leukotriene CysLT1 receptor.

### **Dosage And Administration:**

Adults 15 years of age: One tablet (10mg) once daily at bed time. Children 6-14 years of age: One chewable tablet (5mg) once daily at bed time. Montex may be taken with or without food or as directed by physician. Safety and effectiveness in children younger than 2 years of age have not been established.

### **Contraindications:**

Montelukast is contraindicated in patients who are Hypersensitive to any component of this product.

### **Warning And Precaution:**

Montelukast is not indicated for use in acute asthma attacks. Therapy with Montelukast can be continued during acute exacerbation of asthma. Montelukast should not be used as monotherapy for the treatment and management of exercise induced bronchospasm. There are no adequate and well controlled studies in pregnant women. Montelukast should be used during only if clearly needed. Montelukast is excreted in milk. So caution should be exercised when Montelukast is given to a nursing mother.

### **Side Effects:**

Montelukast has been generally well tolerated. Side effects, which usually are mild, including gastro-intestinal disturbances, dry mouth, thirst; hypersensitivity reactions including anaphylaxis, angioedema and skin reactions; asthenia, dizziness, irritability, restlessness, headache, sleep disorders (insomnia, drowsiness, nightmares); upper respiratory tract infection, fever, arthralgia, myalgia. The overall incidence of side effects reported with montelukast was comparable to placebo.

### **Use in Pregnancy and Lactation:**

There are no adequate and well-controlled studies in pregnant women. Montelukast should be used during pregnancy only if clearly needed. Montelukast is excreted in breast milk. So caution should be exercised when Montelukast is given to a nursing mother.

### **Drug Interaction:**

It is reasonable to employ appropriate clinical monitoring when potent cytochrome P450 enzyme inducers, such as phenobarbital or rifampin, are co-administered with montelukast.

### **Overdosage:**

There were no adverse experiences in the majority of overdosage 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. 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 in cool & dry place below 30°C, protect from light & moisture. Keep out of reach of children.

**Packing:**

Montex 5 tablet: Each box contains 2x10 tablets in blister pack. Montex 10 tablet: Each box contains 1x10 tablets in blister pack.

Manufactured By:

The IBN SINA Pharmaceutical Industry PLC.

Shafipur, Gazipur, Bangladesh.