Montika® Tablets / Sachets
(Montelukast Sodium)

DESCRIPTION:
Montelukast Sodium, the active ingredient in MONTIKA®, is selective and orally active leukotriene receptor antagonist that inhibits the cysteinyl leukotriene CysLT1 receptor.

Montelukast Sodium is described chemically as \([\text{R-(E)-1-[[1-(3-(1H-pyrazol-4-yl)-2-quinolinyl)]ethenyl]phenyl]-3-(1-hydroxy-1-methyl-ethyl)phenylpropyl][bis(hydroxy)cyclopropyl]acetic acid, monosodium salt\].

The empirical formula is C35H33N3O5NaS, and its molecular weight is 608.18.

The structural formula is:

Montelukast Sodium is a hygroscopic, optically active, white to off-white powder. Montelukast Sodium is freely soluble in ethanol, methanol and water and practically insoluble in acetone.

COMPOSITION:

MONTIKA® 4mg Sachets:
Each Sachet contains: Montelukast Sodium USP equivalent to Montelukast Acid . . . 4mg

MONTIKA® 4mg Chewable Tablets:
Each tablet contains: Montelukast Sodium USP equivalent to Montelukast Acid . . . 4mg

MONTIKA® 5mg Chewable Tablets:
Each tablet contains: Montelukast Sodium USP equivalent to Montelukast Acid . . . 5mg

MONTIKA® 10mg Film Coated Tablets:
Each tablet contains: Montelukast Sodium USP equivalent to Montelukast Acid . . . 10mg

CLINICAL PHARMACOLOGY:

Mechanism of action:
The cysteinyl leukotrienes (LTC4, LTD4, LTE4) are products of arachidonic acid metabolism and are released from various cells, including mast cells and eosinophils. These eicosanoids bind to cysteinyl leukotriene (CysLT) receptors. The CysLT type-1 (CysLT1) receptor is found in the human airway (including airway smooth muscle cells and airway macrophages) and on other pro-inflammatory cells (including eosinophils and certain myeloid stem cells). CysLTs have been correlated with the pathophysiology of asthma and allergic rhinitis.

Montelukast is an orally active compound that binds with high affinity and selectivity to the CysLT1 receptor (in preference to other pharmacologically important airway receptors, such as the prostanoid, cholinergic, or β-adrenergic receptor). Montelukast inhibits physiologic actions of LTD4 at the CysLT1 receptor without any agonist activity.

INDICATIONS AND USAGE:

MONTIKA® is indicated for the prophylaxis and chronic treatment of asthma in adults and paediatric patients 12 months of age and older.

Prevention of Exercise-induced bronchoconstriction:
MONTIKA® is indicated for the relief of symptoms of allergic rhinitis (seasonal allergic rhinitis and perennial allergic rhinitis in adults and paediatric patients 6 months of age and older).

DOSAGE & ADMINISTRATION:

In children 6 months to 5 Years of Age:
One sachet of MONTIKA® Paediatric 4mg granules to be taken by mouth each evening.

In children 2 to 5 Years of Age:
One MONTIKA® 4mg chewable tablet to be taken every night.

In children 6 to 14 Years of Age:
One MONTIKA® 5mg chewable tablet to be taken every night.

One MONTIKA® 10mg film coated tablet to be taken every night.

CONTRA-INDICATIONS:

Hypersensitivity to any component of this product.

PRECAUTIONS:

General:
MONTIKA® 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. Therapy with MONTIKA® should not be abruptly discontinued for the prevention of asthma.

MONTIKA® should be continued during acute exacerbations of asthma.

While the use of inhaled corticosteroids may be reduced gradually under medical supervision, MONTIKA® should not be abruptly substituted for inhaled or oral corticosteroids.

MONTIKA® should not be used as monotherapy for the treatment and management of exercise-induced bronchospasm. Patients who have exacerbations of asthma after exercise should continue to use their usual regimen of inhaled (beta)-agonists as prophylaxis and have available for rescue a short acting inhaled (beta)-agonist.

Special Precautions:

Use of MONTIKA® during pregnancy:

Pregnancy Category B, MONTIKA® should be used during pregnancy only if clearly needed.

Use of MONTIKA® during Lactation:

Studies in rats have shown that montelukast is excreted in milk, caution should be exercised when MONTIKA® is given to a nursing mother.

Use of MONTIKA® in Paediatrics:
The safety of MONTIKA® 4mg and 5mg chewable tablets in paediatric patients aged 2 to 14 years with allergic rhinitis is supported by data from studies conducted in paediatric patients aged 2 to 14 years with asthma.

The safety and effectiveness in paediatric patients below the age of 2 years with asthma and allergic rhinitis have not been established.

Use of MONTIKA® in elderly (old age patients):

No over all differences in safety or effectiveness were observed between different age groups.

DRUG INTERACTION:

MONTIKA® may be co-administered with other drugs commonly used for the chronic treatment and prophylaxis of asthma. Since the therapeutic dose of Montelukast has not been found to have clinically significant effects on the pharmacokinetics of the theophylline, prednisone, prednisolone, oral contraceptives (norethindrone/ethinyl estradiol), terfenadine, digoxin, and warfarin. It can be safely co-prescribed with these drugs.

SIDE EFFECTS:

Montelukast is over all well tolerated. Its common side effects include asthma, dyspepsia, dizziness, headache, nasal congestion, cough, and flu like symptoms. In children, diaphoresis, laryngitis, pharyngitis, nausea, etc. might occur. Side effects are usually mild and do not necessitate therapy withdrawal. The incidence of side effect is comparable to placebo.

OVER DOSAGE:

No specific information is available on the treatment of overdosage with MONTIKA®. In chronic asthma studies, Montelukast has been administered at doses up to 200mg/day to adult patients for 22 weeks and in short-term studies up to 900mg/day to patients for approximately a week without clinically important adverse experiences.

It is not known whether Montelukast is removed by peritoneal dialysis or hemodialysis.

STABILITY:

See expiry on the pack.

PRESENTATIONS:

MONTIKA® 4mg sachets in pack of 14’s.

MONTIKA® 4mg chewable tablets in pack of 14’s.

MONTIKA® 5mg chewable tablets in pack of 14’s.

MONTIKA® 10mg film coated tablets in pack of 14’s.

INSTRUCTIONS:

Keep out of reach of children.

Avoid exposure to heat, light and humidity.

Store at 25°C or below.

Improper storage may deteriorate the medicine.

Manufactured by:

SAMS PHARMACEUTICALS (PVT) LTD.