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# Monas®

- Tablet
- Oroflash Tablet
- Chewable Tablet

Montelukast Sodium USP

## COMPOSITION

**Monas® 10:** Each film coated tablet contains Montelukast Sodium USP equivalent to 10 mg Montelukast.
**Monas® 5 OFT:** Each Oroflash tablet contains Montelukast Sodium USP equivalent to 5 mg Montelukast.
**Monas® 4 OFT:** Each Oroflash tablet contains Montelukast Sodium USP equivalent to 4 mg Montelukast.
**Monas® 5:** Each chewable tablet contains Montelukast Sodium USP equivalent to 5 mg Montelukast.
**Monas® 4:** Each chewable tablet contains Montelukast Sodium USP equivalent to 4 mg Montelukast.

## PHARMACOLOGY

Monas® (Montelukast) is a selective and orally active leukotriene receptor antagonist that inhibits the cysteinyl leukotriene receptor ($CysLT_1$). 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. Cysteinyl leukotrienes and leukotriene receptor occupation have been correlated with the pathophysiology of asthma, including airway edema, smooth muscle contraction, and altered cellular activity associated with the inflammatory process, which contribute to the signs and symptoms of asthma.

## INDICATIONS

Monas® is indicated for the prophylaxis and chronic treatment of Asthma, prevention of Exercise-Induced Asthma (EIA) & Relief of symptoms of Allergic Rhinitis (AR) in adults & children.

## DOSAGE AND ADMINISTRATION

**Route of administration :** Oral
**6 months – 6 years :** 4 mg/day in the evening
**6 years – 15 years :** 5 mg/day in the evening
**15 years and older :** 10 mg/day in the evening
Monas® (Montelukast) may be taken with or without food.
**OR AS DIRECTED BY THE PHYSICIAN.**

## CONTRAINDICATIONS

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

## WARNING & PRECAUTIONS

Montelukast is not indicated for use in acute asthma attacks. Therapy with montelukast can be continued during acute exacerbations of asthma. Montelukast should not be used as monotherapy for the treatment and management of exercise-induced bronchospasm.

## SIDE-EFFECTS

***Common side effects :*** Montelukast has been generally well tolerated. Side effects, which usually are mild, including Diarrhoea, Fever, Gastrointestinal discomfort, Headache, Nausea, Upper respiratory tract infection, Vomiting, dizziness, irritability. The overall incidence of side effects reported with montelukast was comparable to placebo.

***Rare side effects :*** Angioedema, impaired concentration, Disorientation, Hallucination, hepatic disorders, memory loss, palpitations.

## ADVERSE DRUG REACTION

Blood and lymphatic system disorders: increased bleeding tendency, thrombocytopenia.
Immune system disorders: hypersensitivity reactions including anaphylaxis, hepatic eosinophilic infiltration.
Neuropsychiatric disorders: agitation, aggressive behavior, anxiousness, depression, insomnia, disorientation, dream abnormalities, hallucinations, irritability, restlessness, somnambulism, suicidal thinking, tremor.
Nervous system disorders: drowsiness, paraesthesia/hypoesthesia, seizures.

## 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 milk. So caution should be exercised when montelukast is given to a nursing mother.

## DRUG INTERACTIONS

***With medicine:*** No dose adjustment is needed when Montelukast is co-administered with Theophylline, Prednisone, Prednisolone, Oral contraceptives, Terfenadine, Digoxin, Warfarin, Gemfibrozil, Itraconazole, Thyroid hormones, Sedative hypnotics, non-steroidal anti-inflammatory agents, Benzodiazepines, Decongestants, and Cytochrome P450 (CYP) enzyme inducers.
***With food & others:*** Drug-Food interactions have not been established.

## OVERDOSE

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

## STORAGE

Store below 30° C temperature, protected from light & moisture.
Keep all medicines out of reach of children.

## PACKING

**Monas® 10 :** Each box contains 2x15 tablets in Alu-Alu blister.
**Monas® 5 OFT :** Each box contains 3x10 Oroflash tablet in Alu-Alu blister.
**Monas® 4 OFT :** Each box contains 3x10 Oroflash tablet in Alu-Alu blister.
**Monas® 5 :** Each box contains 3x10 Chewable tablets in Alu-Alu blister.
**Monas® 4 :** Each box contains 3x10 Chewable tablets in Alu-Alu blister.

* Further information is available on request.

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Manufactured by:
The ACME Laboratories Ltd.
Dhulivita, Dhamrai, Dhaka, Bangladesh
For Health, Vigour and Happiness

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