

Alastar

5mg, 10mg, Tablets/4mg Sachets

الاستار
۱۰.۵ میلی گرام ٹیبلٹیں / ۴ میلی گرام ساکٹس

(Montelukast Sodium)

DESCRIPTION:

Montelukast Sodium is the active ingredients in **Alastar**, orally bioavailable monosodium salt of montelukast, a selective cysteinyl leukotriene receptor antagonist with anti-inflammatory and bronchodilating activities. Montelukast selectively and competitively blocks the cysteinyl leukotriene I (CysLT1) receptor, preventing binding of the inflammatory mediator leukotriene D4 (LTDA).

The empirical formula is $C_{35}H_{36}C_1NNaO_5S_2$, and its molecular weight is 608.18.

COMPOSITION:

■ **Alastar 10mg Tablet**

Each film coated tablet contains:

Montelukast (as sodium).....10 mg USP Specifications

■ **Alastar 5mg Tablet**

Each Chewable tablet contains:

Montelukast (as sodium).....5mg USP Specifications

■ **Alastar 4mg Sachet**

Each Sachets contains:

Montelukast (as sodium).....4mg USP Specifications

CLINICAL PHARMACOLOGY:

Mechanism of Action

Montelukast selectively and competitively blocks the cysteinyl leukotriene 1 (CysLT1) receptor, preventing binding of the inflammatory mediator leukotriene D4 (LTDA). Inhibition of LTDA activity results in inhibition of leukotriene-mediated inflammatory events including: migration of eosinophils and neutrophils; adhesion of leukocytes to vascular endothelium, monocyte and neutrophil aggregation; increased airway edema; increased capillary permeability; and bronchoconstriction. The CysLT 1 receptor is found in a number of tissues including spleen, lung, placenta, small intestine, and nasal mucosa, and in a variety of cell types including monocyte/macrophages, mast cells, eosinophils, CD34-positive hemopoietic progenitor cells, neutrophils and endothelial cells.

INDICATION AND USAGE:

Alastar is indicated for prophylaxis and chronic treatment of asthma in adults and pediatric patients 12 months of age and older.

Alastar is indicated for prevention of exercise-induced bronchoconstriction in patients 15 years of age and older. **Alastar** is indicated for relief of symptoms of allergic rhinitis (seasonal allergic rhinitis in adults and pediatric patients 2 years of age and older, and perennial allergic rhinitis in adult and pediatric patients 6 months of age and older).

DOSAGE AND ADMINISTRATION:

Adults and Adolescents ≥ 15 years (Asthma or Asthma and Concomitant Seasonal Allergic Rhinitis): One 10-mg tablet daily to be taken in the evening.

Children 6 to 14 years: One 5mg chewable tablet daily to be taken in the evening.

CONTRAINDICATIONS:

Hypersensitivity to Montelukast sodium.

WARNINGS AND PRECAUTIONS:

Talk to your doctor or pharmacist before taking **Alastar**. If your asthma or breathing gets worse, tell your doctor immediately. Oral **Alastar** is not meant to treat acute asthma attacks. If an attack occurs, follow the instructions your doctor has given you. Always have your inhaled rescue medicine for asthma attacks with you. It is important that you or your child take all asthma medications prescribed by your doctor. **Alastar** should not be substituted for other asthma medications

Special Precautions:

Alastar with food and drink; **Alastar** 10 mg may be taken with or without food.

Use in pregnancy: Women who are pregnant or intend to become pregnant should consult their doctor before taking **Alastar**. Your doctor will assess whether you can take **Alastar** during this time.

Use in breast-feeding: It is not known if **Alastar** appears in breast milk. You should consult your doctor before taking **Alastar** if you are breast-feeding or intend to breast-feed.

Driving and using machines; **Alastar** is not expected to affect your ability to drive a car or operate machinery. **DRUG INTERACTIONS:**

DRUG INTERACTIONS:

Alastar may be administered with other therapies routinely used in the prophylaxis and chronic treatment of asthma, and in the treatment of allergic rhinitis. In drug-interactions studies, the recommended clinical dose of **Alastar** did not have clinically important effects on the pharmacokinetics of the following drugs: Theophylline, prednisone, prednisolone, oral contraceptives (ethinyl estradiol/norethindrone), terfenadine, digoxin and warfarin.

POSSIBLE SIDE EFFECTS:

Like all medicines, this medicine can cause side effects, although not everybody gets them. In clinical studies with **Alastar** 10 mg film-coated tablets, the most commonly reported side effects (occurring in at least 1 of 100 patients and less than 1 of 10 patients treated) thought robe related to **Alastar** were: Abdominal pain and Headache. These were usually mild and occurred at a greater frequency in patients treated with **Alastar**.

Upper respiratory infection. Increased bleeding tendency.

Allergic reactions including rash, swelling of the face, lips, tongue, and/or throat.

OVERDOSE:

No specific information is available on the treatment of over dosage with **Alastar**. In chronic asthma studies, **Alastar** 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 one week without clinically important adverse experiences.

STORAGE & INSTRUCTIONS:

Keep out of reach of children & Store below 30°C.

Protect from sunlight & moisture

Improper storage may deteriorate the medicine

Do not use this medicine after the expiry date which is stated on the blister.

PRESENTATION:

Alastar 5mg chewable Tablet in pack of 14's

Alastar 10mg film coated Tablet in pack of 14's

Alastar 4mg Sachet in pack of 14's

الاسٹار گولیاں اساتے

خوراک: ڈاکٹر ہدایت کے مطابق استعمال کریں۔

ہدایت: بچوں کی پہنچ سے دور رکھیں۔

دوا کو دھوپ، گرمی اور نمی سے محفوظ رکھیں۔ ۳۰ ڈگری سینٹی گریڈ

سے کم درجہ حرارت پر رکھیں ورنہ دوا خراب ہو جائے گی۔

Manufactured by :



PHARMA LORD

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