

ASTHATOR TABLET®

Montelukast Sodium (4 mg, 5mg, 10mg)

What is in this leaflet

1. What Asthator is used for
2. How Asthator works
3. Before you use Asthator
4. How to use Asthator
5. While you are using it
6. Side effects
7. Storage and Disposal of Asthator
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

What Asthator is used for

Asthator is indicated in adults and pediatrics 2 years of age and older for:

- The prevention and chronic treatment of asthma
- The relief of day time and night time symptoms of allergic rhinitis (inflammation of the mucous membrane inside the nose).

How Asthator works

Asthator contains active ingredient montelukast. Montelukast is a leukotriene receptor antagonist that blocks substances called leukotrienes. Leukotrienes cause narrowing and swelling of airways in the lungs and also cause allergy symptoms. By blocking leukotrienes, it improves asthma symptoms, helps control asthma and improves allergy symptoms.

Before you use Asthator

- When you must not use it

Do not use Asthator if you are hypersensitive to the active substance or to any of the excipients.

- Pregnancy and lactation

- Do not take Asthator if you are pregnant, trying to get pregnant or think you may be pregnant.
- Do not take Asthator if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

- Before you start to use it

- Oral Asthator should not be used to treat acute asthma attacks.
- Asthator should not be abruptly substituted for inhaled or oral corticosteroids.

- If you were on therapy with anti-asthma agents including Asthator, you may present with systemic eosinophilia (a higher than normal level of eosinophils - a type of disease-fighting white blood cell), sometimes presenting with clinical features of vasculitis (an inflammation of blood vessels) consistent with Churg-Strauss syndrome, a condition which is often treated with systemic corticosteroid therapy.

- Inform your doctor if you have eosinophilia, vasculitic rash, worsening pulmonary (lungs) symptoms, cardiac (heart) complications, and/or neuropathy (damages to nerve)

- Asthator contains aspartame, a source of phenylalanine: Tell your doctor if you have phenylketonuria (a rare inherited disorder that causes an amino acid called phenylalanine to build up in your body).

Pregnancy category B:

Asthator should be used during pregnancy only if clearly needed.

Nursing Mothers

It is not known if Asthator is excreted in human milk. Because many medicine are excreted in human milk, caution should be exercised if you are breastfeeding.

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Please tell your doctor or pharmacist if you are taking or have recently taken other medicines, including those obtained without a prescription.

Tell your doctor if you are taking the following medicines before starting Asthator:

- Phenobarbital (used for treatment of epilepsy)
- Phenytoin (used for treatment of epilepsy)
- Rifampicin (used to treat tuberculosis and some other infections)

How to use Asthator

- How much to use

Adults and Adolescents 15 Years of Age and Older with Asthma or Allergic Rhinitis.

The dosage is one 10-mg tablet daily.

Pediatrics 6 to 14 Years of Age with Asthma or Allergic Rhinitis.

The dosage is one 5-mg tablet daily. No dosage adjustment within this age group is necessary.

Pediatrics 2 to 5 Years of Age with Asthma or Allergic Rhinitis

The dosage for is one 4-mg tablet daily.

- When to use it

Asthator should be taken once daily. For asthma, the dose should be taken in the evening. For allergic rhinitis, the time of administration may be individualized to suit your needs. If you have both asthma and allergic rhinitis you should take only one tablet daily in the evening.

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking Asthator for as long as your doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

There were no side effects reported in the majority of overdose reports. The most frequently occurring symptoms reported with overdose included abdominal pain, somnolence (sleepiness), thirst,

ASTHATOR TABLET®

Montelukast Sodium (4mg, 5mg, 10mg)

headache, vomiting, and psychomotor hyperactivity.

While you are using it

- Things you must do

- Take your medicine exactly as your doctor has told you.
- Tell all the doctors, dentists and pharmacists treating you that you are taking Asthator.
- Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

- Do not stop taking the medicine unless advised by your doctor.
- Do not take any new medicines without consulting your doctor.
- Do not give Asthator to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

Be careful when engaging in activities requiring mental alertness such as driving a car or operating machinery until you know how this medicine affects you.

Side effects

Like all medicines, Asthator can cause side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Those side effects are:

- Increased bleeding tendency
- Hypersensitivity reactions including anaphylaxis (serious allergic reaction)
- Nightmares
- Hallucinations
- Insomnia
- Restlessness
- Aggressive behavior
- Tremor

- Depression
- Suicidal thinking and behavior
- Dizziness
- Drowsiness
- Paraesthesia (sensation of tingling, tickling, pricking, or burning of a person's skin) /hypoesthesia (reduced sense of touch or sensation).
- Seizure
- Palpitations (feeling that your heart is beating too hard or too fast).
- Diarrhoea
- Dry mouth
- Dyspepsia (indigestion).
- Nausea
- Vomiting
- Cholestatic hepatitis (liver inflammation)
- Elevated levels of serum transaminases (ALT, AST)
- Angioedema (swelling of the deeper layers of the skin).
- Bruising
- Urticaria (hives, welts or nettle rash – is a raised, itchy rash that appears on the skin).
- Pruritus (Itch).
- Rash
- Erythema nodosum (inflammation of the fat cells under the skin).
- Arthralgia (joint pain).
- Myalgia (muscle pain) including muscle cramps
- Asthenia/fatigue
- Malaise
- Oedema (Swelling caused by fluid retention in the body).
- Very rare cases of Churg-Strauss Syndrome (CSS) (form of vasculitis which is inflammation of blood vessels).
- Thrombocytopenia (platelets deficiency in the blood)

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers →Reporting).

Storage and Disposal of Asthator

- Storage

- Keep out of the reach and sight of children.
- Store below 30°C. Protected from moisture.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

Asthator 4mg Chewable Tablet
Pink colored, oval biconvex shaped, uncoated tablets, with break line on both the sides.

Asthator 5 mg Chewable Tablet

Pink colored, round shaped, uncoated tablets, with break line on both the sides.

Asthator 10 mg Tablet

Light brown colored, round biconvex shaped, uncoated tablets, with break line on both the sides.

- Ingredients

Active ingredient
Montelukast sodium

Inactive ingredients
Mannitol (Perlitol SD 200)
Cellulose Micrycrystalline (Avicel PH 102)
Croscarmellose Sodium
Aspartame
Cherry Flavour
Ferric Oxide Red
Ferric Oxide Yellow (in Asthator Tablet 10mg)
Magnesium Stearate

- MAL numbers:

Asthator 4 mg Chewable Tablet:
MAL11010027A
Asthator 5 mg Chewable Tablet:
MAL11010028A
Asthator 10 mg Tablet
MAL11010029A

ASTHATOR TABLET[®]

Montelukast Sodium (4mg, 5mg, 10mg)

Manufacturer

TORRENT PHARMACEUTICALS
LTD.
Indrad 382 721, District: Mehsana
INDIA.

Product Registration Holder

Laboratories Torrent (Malaysia) Sdn
Bhd.,
Suite E-08-08 Plaza Mont Kiara,
No. 2 Jalan Kiara, Mont Kiara.
50480 Kuala Lumpur Malaysia.

Date of revision

15/12/2015

Serial Number

BPFK (R4/1)101215/00490