

MONULAIR CHEWABLE TABLET 5MG

Montelukast Sodium 5mg

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What Monulair Chewable Tablet 5mg is used for

Your doctor has prescribed Monulair Chewable Tablet 5mg to treat:

- Asthma, including preventing your asthma symptoms during the day and night. Monulair Chewable Tablet 5mg also prevents the narrowing of airways triggered by exercise.
- Allergic rhinitis (seasonal and perennial), including daytime and nighttime symptoms: nasal congestion, runny nose, nasal itching, and sneezing; nasal congestion upon awakening, difficulty going to sleep, and nighttime awakenings; tearing, itchy, red, and puffy eyes.

Asthma is a long term disease with characteristics that include:

- Difficulty breathing because of narrowed airways. This narrowing of airways worsens and improves in response to various conditions.
- Sensitive airways that react to many things, such as cigarette smoke, pollen, cold air, or exercise.
- Swelling (inflammation) in the lining of the airways.
- Symptoms such as coughing, wheezing and chest tightness.

There are two types of allergic

rhinitis:

- Seasonal allergic rhinitis (also known as hay fever) is triggered by outdoor allergens e.g. airborne pollens from trees, grasses and weeds.
- Perennial allergic rhinitis may occur year-round and is generally triggered by indoor allergens such as dust mites, animal dander, and/ or mold spores.

How Monulair Chewable Tablet 5mg works

Monulair Chewable Tablet 5mg is a leukotriene receptor antagonist that blocks substances called leukotrienes. Leukotrienes cause narrowing and swelling of airways in the lungs. By blocking leukotrienes, Monulair Chewable Tablet 5mg improves asthma symptoms and helps control asthma.

Before you use Monulair Chewable Tablet 5mg

- When you must not use it

Do not take Monulair Chewable Tablet 5mg if you or your child is allergic (hypersensitive) to montelukast or any of the other ingredients of Monulair Chewable Tablet 5mg.

- Before you start to use it

Tell your doctor about any medical problems or allergies you or your child has now or has had.

- Taking other medicines

Some medicines may affect how Monulair Chewable Tablet 5mg works, or Monulair Chewable Tablet 5mg may affect how other medicines work. Please tell your doctor or pharmacist if you or your child is taking or has recently taken other medicines such as gemfibrozil, prednisolone, repaglinide, phenytoin, phenobarbital and rifampicin, or those obtained without a prescription.

How to use Monulair Chewable Tablet 5mg

- How much to use

You or your child should take only one tablet of Monulair Chewable Tablet 5mg once a day as prescribed by your doctor.

- When to use it

It should be taken even when you or your child has no symptoms or has an acute asthma attack.

Always take Monulair Chewable Tablet 5mg with or without food in the evening, or as your doctor advised. You should check with your doctor or pharmacist if you are not sure.

- How long to use it

Monulair Chewable Tablet 5mg can treat you or your child's asthma only if you or your child continues to take it. It is important to continue taking Monulair Chewable Tablet 5mg for as long as your doctor prescribes. It will help control you or your child's asthma.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

- If you forget to take it

Try to take Monulair Chewable Tablet 5mg as prescribed. However, if you or your child misses a dose, just resume the usual schedule of one tablet once daily. Do not take a double dose to make up for a forgotten dose.

- If you use too much (overdose)

Contact your doctor immediately for advice. There were no side effects reported in the majority of overdose reports.

While you are using it

- Things you must do

- If you or your child's asthma or breathing gets worse, tell your doctor immediately.
- Monulair Chewable Tablet 5mg is not meant to treat acute asthma attacks. If an attack occurs, follow the instructions your doctor has given you or your child. 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. Monulair Chewable Tablet 5mg should not be used instead of other asthma medications your doctor has prescribed for you or your child.

- Things you must not do

You or your child should not take acetyl-salicylic acid (aspirin) or anti-inflammatory medicines (also known as non-steroidal anti-inflammatory drugs or NSAIDs) if they make your asthma worse.

- Things to be careful of

Use in pregnancy

Women who are pregnant or intend to become pregnant should consult their doctor before taking Monulair Chewable Tablet 5mg. Your doctor will assess whether you can take Monulair Chewable Tablet 5mg during this time.

Use in breast-feeding

It is not known if Monulair Chewable Tablet 5mg appears in breast milk. You should consult your doctor before taking Monulair Chewable Tablet 5mg if you are breast-feeding or intend to breast-feed.

Driving and using machines

Monulair Chewable Tablet 5mg is not expected to affect your ability to drive a car or operate machinery. However, individual responses to medication may vary. Certain side effects (such as dizziness and drowsiness) may affect some patients' ability to drive or operate machinery.

Use in phenylketonurics

Monulair Chewable Tablet 5mg contain aspartame, a source of phenylalanine. If your child has phenylketonuria (a rare, hereditary disorder of the metabolism) you should take into account that each Monulair Chewable Tablet 5mg contains phenylalanine.

Side Effects

Like all medicines, Monulair Chewable Tablet 5mg can cause side effects, although not everybody gets them. Common side effects includes abdominal pain, headache, diarrhea, hyperactivity, scaly and itchy skin, and rash. Other side effects includes:

- respiratory infection
- increased bleeding tendency
- allergic reactions [including swelling of the face, lips, tongue, and/ or throat (which may cause trouble breathing or swallowing), hives, rash, and itching]
- behavior and mood related changes [agitation including aggressive behavior or hostility, depression, dream abnormalities, feeling anxious, hallucinations, insomnia, irritability, restlessness, sleep walking, suicidal thoughts and actions, tremor]
- dizziness, drowsiness, pins and needles/ numbness, very rarely seizure
- palpitations
- nose bleed
- dyspepsia, nausea, vomiting
- hepatitis
- bruising, severe skin reactions that may occur without warning
- joint pain, muscle aches and muscle cramps
- weakness/ tiredness
- swelling
- fever

Tell your healthcare provider right away if you notice any of the following behavior and mood-related changes:

- Obsessive-compulsive symptoms

Ask your doctor or pharmacist for more information about side effects. 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.

You may report any side effects or adverse drug reactions directly to the National Centre for adverse Drug Reaction Monitoring by visiting the website npra.gov.my (Consumers→

Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Monulair Chewable Tablet 5mg

- Storage

Store below 30°C in the original package in order to protect from light and moisture. Keep out of the reach of children.

Do not use this medicine after the date shown by the six numbers following EXP on the blister. The first two numbers indicate the month; the last four numbers indicate the year. This medicine expires at the end of the month shown.

- 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

Light pink coloured, speckled, round, biconvex shaped, chewable tablets debossed with '1' on one side and '113' on the other side.

- Ingredients

Each tablet contains Montelukast Sodium 5mg. In addition, each tablet also contains inactive ingredients:

- mannitol,
- microcrystalline cellulose,
- ferric oxide red,
- hydroxypropyl cellulose,
- croscarmellose sodium,
- cherry flavour,
- aspartame
- magnesium stearate

- MAL number:

MAL17015022AZ

Manufacturer

Hetero Labs Ltd., Unit V,
Survey No. 439, 440, 441 & 458,
TSIIC Formulation SEZ,
Polepally village, Jadcherla Mandal,
Mahaboob Nagar District, Telangana,
India.

Product Registration Holder

Camber Laboratories Sdn. Bhd.
Unit E-13A-02, Menara SUEZCAP 2,
No 2, KL Gateway, Jalan Kerinchi,
Gerbang Kerinchi Lestari, 59200 Kuala
Lumpur, Malaysia

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