

Patient Information
Montelukast Sodium Oral Granules
(mon te loo' kast soe' dee um)

Read the Patient Information Leaflet that comes with montelukast sodium before you start taking it and each time you get a refill. There may be new information. This leaflet does not take the place of talking with your healthcare provider about your medical condition or your treatment.

What is montelukast sodium?

- Montelukast sodium is a prescription medicine that blocks substances in the body called leukotrienes. This may help to improve symptoms of asthma and allergic rhinitis. Montelukast sodium does not contain a steroid.

Montelukast sodium is used to:

1. Prevent asthma attacks and for the long-term treatment of asthma in adults and children ages 12 months and older.
Do not take montelukast sodium if you need relief right away for a sudden asthma attack. If you get an asthma attack, you should follow the instructions your healthcare provider gave you for treating asthma attacks.
2. Help control the symptoms of allergic rhinitis (sneezing, stuffy nose, runny nose, itching of the nose). Montelukast sodium is used to treat:
 - outdoor allergies that happen part of the year (seasonal allergic rhinitis) in adults and children ages 2 years and older, **and**
 - indoor allergies that happen all year (perennial allergic rhinitis) in adults and children ages 6 months and older.

Who should not take montelukast sodium?

Do not take montelukast sodium if you are allergic to any of its ingredients. See the end of this leaflet for a complete list of the ingredients in montelukast sodium oral granules.

What should I tell my healthcare provider before taking montelukast sodium?

Before taking montelukast sodium, tell your healthcare provider if you:

- are allergic to aspirin
- have any other medical conditions
- are pregnant or plan to become pregnant. Talk to your doctor if you are pregnant or plan to become pregnant, as montelukast sodium may not be right for you.
- are breast-feeding or plan to breast-feed. It is not known if montelukast sodium passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby while taking montelukast sodium.

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Some medicines may affect how montelukast sodium works, or montelukast sodium may affect how your other medicines work.

How should I take montelukast sodium?

For anyone who takes montelukast sodium:

- Take montelukast sodium exactly as prescribed by your healthcare provider. Your healthcare provider will tell you how much montelukast sodium to take, and **when to take it**.
- Do not stop taking montelukast sodium or change when you take it without talking with your healthcare provider.
- You can take montelukast sodium with food or without food. See the information below in the section "How should I give montelukast sodium oral granules to my child?" for information about what foods and liquids can be taken with montelukast sodium oral granules.
- **If you or your child misses a dose of montelukast sodium, just take the next dose at your regular time.** Do not take 2 doses at the same time.
- If you take too much montelukast sodium, call your healthcare provider or a Poison Control Center right away.

For adults and children 12 months of age and older with asthma:

- Take montelukast sodium 1 time each day, in the evening. Continue to take montelukast sodium every day for as long as your healthcare provider prescribes it, even if you have no asthma symptoms.
- Tell your healthcare provider right away if your asthma symptoms get worse, or if you need to use your rescue inhaler medicine more often for asthma attacks.
- **Do not take montelukast sodium if you need relief right away from a sudden asthma attack.** If you get an asthma attack, you should follow the instructions your healthcare provider gave you for treating asthma attacks.
- Always have your rescue inhaler medicine with you for asthma attacks.
- Do not stop taking or lower the dose of your other asthma medicines unless your healthcare provider tells you to.

For adults and children 2 years of age and older with seasonal allergic rhinitis, or for adults and children 6 months of age and older with perennial allergic rhinitis:

- Take montelukast sodium 1 time each day, at about the same time each day.

How should I give montelukast sodium oral granules to my child?

Give montelukast sodium oral granules to your child exactly as instructed by your healthcare provider. Do not open the packet until ready to use.

Montelukast sodium 4 mg (montelukast) oral granules can be given:

- right in the mouth; or
- dissolved in 1 teaspoonful (5 mL) of cold or room temperature baby formula or breast milk; or
- mixed with 1 spoonful of one of the following soft foods at cold or room temperature: applesauce, mashed carrots, rice, or ice cream.

Give the child all of the mixture right away, within 15 minutes.

Do not store any leftover montelukast sodium mixture (oral granules mixed with food, baby formula, or breast milk) for use at a later time. Throw away any unused portion.

Do not mix montelukast sodium oral granules with any liquid drink other than baby formula or breast milk. Your child may drink other liquids after swallowing the mixture.

What is the dose of montelukast sodium?

The dose of montelukast sodium prescribed for your or your child's condition is based on age:

- 6 to 23 months: one packet of 4 mg oral granules.
- 2 to 5 years: one packet of 4 mg oral granules.

What should I avoid while taking montelukast sodium?

If you have asthma and aspirin makes your asthma symptoms worse, continue to avoid taking aspirin or other medicines called non-steroidal anti-inflammatory drugs (NSAIDs) while taking montelukast sodium.

What are the possible side effects of montelukast sodium?

Montelukast sodium may cause serious side effects.

- **Behavior and mood-related changes.** Tell your healthcare provider right away if you or your child have any of these symptoms while taking montelukast sodium:
 - agitation including aggressive behavior or hostility
 - attention problems
 - bad or vivid dreams
 - depression
 - disorientation (confusion)
 - feeling anxious
 - hallucinations (seeing or hearing things that are not really there)
 - irritability
 - memory problems
 - obsessive-compulsive symptoms
 - restlessness
 - sleep walking
 - suicidal thoughts and actions (including suicide)
 - tremor
 - trouble sleeping
 - uncontrolled muscle movements
- **Increase in certain white blood cells (eosinophils) and possible inflamed blood vessels throughout the body (systemic vasculitis).**

Rarely, this can happen in people with asthma who take montelukast sodium. This sometimes happens in people who also take a steroid medicine by mouth that is being stopped or the dose is being lowered.

Tell your healthcare provider right away if you get one or more of these symptoms:

- a feeling of pins and needles or numbness of arms or legs
- a flu-like illness
- rash
- severe inflammation (pain and swelling) of the sinuses (sinusitis)

The most common side effects with montelukast sodium include:

- upper respiratory infection
- fever
- headache
- sore throat
- cough
- stomach pain
- diarrhea
- earache or ear infection
- flu
- runny nose
- sinus infection

Other side effects with montelukast sodium include:

- increased bleeding tendency, low blood platelet count
- allergic reactions [including swelling of the face, lips, tongue, and/or throat (which may cause trouble breathing or swallowing), hives and itching]
- dizziness, drowsiness, pins and needles/numbness, seizures (convulsions or fits)
- palpitations
- nose bleed, stuffy nose, swelling (inflammation) of the lungs
- heartburn, indigestion, inflammation of the pancreas, nausea, stomach or intestinal upset, vomiting
- hepatitis
- bruising, rash, severe skin reactions (erythema multiforme, Stevens-Johnson syndrome/toxic epidermal necrolysis) that may occur without warning
- joint pain, muscle aches and muscle cramps
- bedwetting in children
- tiredness, swelling

Tell your healthcare provider if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of montelukast sodium. For more information ask your healthcare provider or pharmacist.

Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store montelukast sodium oral granules?

- Store montelukast sodium oral granules at 20°–25° C (68°–77° F), excursions permitted to 15°–30° (59°–86° F).
- Keep montelukast sodium oral granules in the packet it comes in.
- Keep montelukast sodium oral granules in a dry place and away from light.

General Information about the safe and effective use of montelukast sodium

Medicines are sometimes prescribed for purposes other than those mentioned in Patient Information Leaflets. Do not use montelukast sodium for a condition for which it was not prescribed. Do not give montelukast sodium to other people even if they have the same symptoms you have. It may harm them. **Keep montelukast sodium and all medicines out of the reach of children.**

This leaflet summarizes information about montelukast sodium. If you would like more information, talk to your healthcare provider. You can ask your pharmacist or healthcare provider for information about montelukast sodium that is written for health professionals.

What are the ingredients in montelukast sodium oral granules?

Active ingredient: montelukast sodium

Inactive ingredients:

- 4 mg oral granules: hypromellose, magnesium stearate, and mannitol.

Rx only

Manufactured by:
Dr. Reddy's Laboratories Limited
Bachupally – 500 090 INDIA