



MEDICATION GUIDE

Montelukast Sodium (mon te loo' kast soe' dee um) Tablets USP and Montelukast Sodium (mon te loo' kast soe' dee um) Chewable Tablets USP
Montelukast Sodium (mon te loo' kast soe' dee um) Oral Granules USP

What is the most important information I should know about montelukast sodium?

Serious mental health problems have happened in people taking montelukast sodium or even after treatment has stopped. This can happen in people with or without a history of mental health problems. Stop taking montelukast sodium and tell your healthcare provider right away if you or your child have any unusual changes in behavior or thinking, including any of these symptoms:

- agitation, including aggressive behavior or hostility
- attention problems
- bad or vivid dreams
- depression
- disorientation (confusion)
- feeling anxious
- irritability
- hallucinations (seeing or hearing things that are not really there)
- memory problems
- obsessive-compulsive symptoms
- restlessness
- suicidal thoughts and actions (including suicide)
- tremor
- trouble sleeping
- uncontrolled muscle movements
- sleep walking
- stuttering

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 inflammation of the lining of the nose (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 have an asthma attack, you should follow the instructions your healthcare provider gave you for treating asthma attacks.
2. Prevent exercise-induced asthma in people 6 years of age and older.
3. Help control the symptoms of allergic rhinitis such as sneezing, stuffy nose, runny nose, and itching of the nose. Montelukast sodium is used to treat the following in people who have already taken other medicines that did not work well enough or in people who could not tolerate other medicines:
 - 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.

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

Before taking Montelukast Sodium, tell your healthcare provider about all your medical conditions, including if you:

- are allergic to aspirin.
- have phenylketonuria. Montelukast sodium chewable tablets contain aspartame, a source of phenylalanine.
- have or have had mental health problems.
- are pregnant or plan to become pregnant. Talk to your healthcare provider if you are

pregnant or plan to become pregnant, montelukast sodium may not be right for you.

- are breastfeeding or plan to breastfeed. 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 over the counter 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:

- Read the detailed **Instructions for Use** that comes with montelukast sodium oral granules.
- 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.**
- Stop taking montelukast sodium and tell your healthcare provider right away if you or your child have any unusual changes in behavior or thinking.
- You can take montelukast sodium with food or without food. See the section **“How can I give montelukast sodium oral granules to my child?”** in the **Instructions for Use** 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 tablets, call your healthcare provider 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.
- Always have your rescue inhaler medicine with you for asthma attacks.
- Continue to take your other asthma medicines as prescribed unless your healthcare provider tells you to change how you take these medicines.

For people 6 years of age and older for the prevention of exercise-induced asthma:

- Take montelukast sodium at least 2 hours before exercise.
- Always have your rescue inhaler medicine with you for asthma attacks.
- If you take montelukast sodium every day for chronic asthma or allergic rhinitis, **do not** take another dose to prevent exercise-induced asthma. Talk to your healthcare provider about your treatment for exercise-induced asthma.
- **Do not take 2 doses of montelukast sodium within 24 hours (1 day).**

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

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

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, including:

- See **“What is the most important information I should know about montelukast sodium?”**
- **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 of montelukast sodium include:

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

These are not all the possible side effects of montelukast sodium.

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

How should I store montelukast sodium?

- Store montelukast sodium at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].
- Keep montelukast sodium in the package it comes in.
- Keep montelukast sodium in a dry place and keep it away from light.
- **Keep montelukast sodium and all medicines out of the reach of children.**

General information about the safe and effective use of montelukast sodium.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. 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.

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?

Active ingredient: Montelukast Sodium USP

Inactive ingredients:

- **4-mg oral granules:** mannitol, hydroxypropyl cellulose, Tribasic Sodium phosphate and magnesium stearate.
- **10-mg tablet:** croscarmellose sodium, ferric oxide red, ferric oxide yellow, hydroxypropyl cellulose, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose and titanium dioxide.
- **4-mg and 5-mg chewable tablets:** aspartame, cellulose microcrystalline, cherry flavor, croscarmellose sodium, ferric oxide red, magnesium stearate, mannitol.

People with Phenylketonuria: Montelukast sodium 4-mg chewable tablets contain 0.168 mg of phenylalanine, and montelukast sodium 5-mg chewable tablets contain 0.210 mg of phenylalanine.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

INSTRUCTIONS FOR USE Montelukast Sodium mon te loo' kast soe' dee um oral granules, USP

This Instructions for Use contains information on how to use montelukast sodium oral granules.

Important Information:

- Before giving a dose of montelukast sodium oral granules, read this Instructions for Use to be sure you prepare and give the oral granules correctly.
- Give montelukast sodium oral granules to your child exactly as instructed by your healthcare provider.
- Stop giving montelukast sodium and tell your healthcare provider right away if your child has any unusual changes in behavior or thinking.
- Continue to give your child their asthma medicines as prescribed, unless your healthcare provider tells you to change how you give these medicines.
- You can give montelukast sodium oral granules with food or without food.

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

- **Do not** open the packet until ready to use.
- There are different ways you can give montelukast sodium 4-mg oral granules. You should choose the best method for your child:
 - right into the mouth
 - dissolved in 1 teaspoonful (5 mL) of cold or room temperature baby formula or breast milk
 - 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 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.

How should I store montelukast sodium?

- Store montelukast sodium at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep montelukast sodium in the package it comes in.
- Keep montelukast sodium in a dry place and keep it away from light.
- **Keep montelukast sodium and all medicines out of the reach of children.**

TORRENT PHARMA

Manufactured by:
Torrent Pharmaceuticals LTD., India.

Manufactured for:
Torrent Pharma INC., Basking Ridge, NJ 07920.

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