MEDICATION GUIDE
Montelukast Sodium Tablets, USP
(mon te loo′kast soe′dee um)

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

Serious mental health problems have happened in people taking montelukast sodium tablets or even after treatment has stopped. This can happen in people with or without a history of mental health problems. Stop taking montelukast sodium tablets 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
- sleep walking
- stuttering
- suicidal thoughts and actions (including suicide)
- tremor
- trouble sleeping
- uncontrolled muscle movements

What ar e montelukast sodium tablets?

Montelukast sodium tablets are 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 tablets does not contain a steroid. Montelukast sodium tablets are used to:

1. Prevent asthma attacks and for the long-term treatment of asthma in adults and adolescents age 15 years and older. **Do not take montelukast sodium tablets 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 15 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 tablets are 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 adolescents age 15 years and older, **and**
   - indoor allergies that happen all year (perennial allergic rhinitis) in adults and adolescents age 15 years and older.

Do not take montelukast sodium tablets 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 tablets.

Before taking montelukast sodium tablets, tell your healthcare provider about all your medical conditions, including if you:

- are allergic to aspirin.
- 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 tablets 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 tablets.

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 tablets works, or montelukast sodium tablets may affect how your other medicines work.

How should I take montelukast sodium tablets?

For **anyone** who takes montelukast sodium tablets:

- Take montelukast sodium tablets exactly as prescribed by your healthcare provider. Your healthcare provider will tell you how much montelukast sodium tablets to take, and **when to take it**.
- Stop taking montelukast sodium tablets 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 tablets with food or without food.
- **If you or your child misses a dose of montelukast sodium tablets, 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 adolescents 15 years of age and older with asthma:

- Take montelukast sodium tablets 1 time each day, in the evening. Continue to take montelukast sodium tablets 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 15 years of age and older for the prevention of exercise-induced asthma:

- Take montelukast sodium tablets at least 2 hours before exercise.
- Always have your rescue inhaler medicine with you for asthma attacks.

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- If you take montelukast sodium tablets 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 tablets within 24 hours (1 day).**

For anyone 15 years of age and older with seasonal allergic rhinitis, or with perennial allergic rhinitis:

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

What should I avoid while taking montelukast sodium tablets?

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 tablets.

What are the possible side effects of montelukast sodium tablets?

Montelukast sodium tablets may cause serious side effects, including:

- See **"What is the most important information I should know about montelukast sodium tablets?"**
- **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 tablets. 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 tablets 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 tablets. 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 tablets?

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

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

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use montelukast sodium tablets for a condition for which it was not prescribed. Do not give montelukast sodium tablets 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 tablets that is written for health professionals.

What are the ingredients in montelukast sodium tablets?

Active ingredient: montelukast sodium

Inactive ingredients:

- **10 mg tablets:** microcrystalline cellulose, lactose monohydrate, croscarmellose sodium, hydroxypropyl cellulose, and magnesium stearate. The film coating consists of: hydroxypropyl methylcellulose, hydroxypropyl cellulose, titanium dioxide, red ferric oxide, and yellow ferric oxide.

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

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