

## Patient Information

# MONTELUKAST SODIUM CHEWABLE TABLETS (montelukast sodium)

Read the Patient Information Leaflet that comes with montelukast sodium chewable tablets 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 are montelukast sodium chewable tablets?

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

Montelukast sodium chewable tablets are used to:

- Prevent asthma attacks and for the long-term treatment of asthma in adults and children ages 2 years and older.  
**Do not take montelukast sodium chewable tablets 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.
- Prevent exercise-induced asthma in people 15 years of age and older.
- Help control the symptoms of allergic rhinitis (sneezing, stuffy nose, runny nose, itching of the nose). Montelukast sodium chewable tablets are 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 2 years and older.

### Who should not take montelukast sodium chewable tablets?

Do not take montelukast sodium chewable tablets 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 chewable tablets.

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

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

- are allergic to aspirin
- have phenylketonuria. Montelukast sodium chewable tablets contain aspartame, a source of phenylalanine
- 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 chewable tablets 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 chewable tablets.

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

### How should I take montelukast sodium chewable tablets?

#### For anyone who takes montelukast sodium chewable tablets:

- Take montelukast sodium chewable tablets exactly as prescribed by your healthcare provider. Your healthcare provider will tell you how much montelukast sodium chewable tablets to take, and **when to take it**.
- Do not stop taking montelukast sodium chewable tablets or change when you take it without talking with your healthcare provider.
- You can take montelukast sodium chewable tablets with food or without food.
- If you or your child misses a dose of montelukast sodium chewable 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 chewable tablets, call your healthcare provider or a Poison Control Center right away.

#### For adults and children 2 years of age and older with asthma:

- Take montelukast sodium chewable tablets 1 time each day, in the evening. Continue to take montelukast sodium chewable 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.
- Do not take montelukast sodium chewable tablets 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 patients 15 years of age and older for the prevention of exercise-induced asthma:

- Take montelukast sodium chewable tablets at least 2 hours before exercise.
- Always have your rescue inhaler medicine with you for asthma attacks.
- If you take montelukast sodium chewable 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 chewable tablets within 24 hours (1 day).**

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

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


### What is the dose of montelukast sodium chewable tablets?

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

- 2 to 5 years: one 4-mg chewable tablet.
- 6 to 14 years: one 5-mg chewable tablet.
- 15 years and older: 10-mg.

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**What should I avoid while taking montelukast sodium chewable 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 chewable tablets.

**What are the possible side effects of montelukast sodium chewable tablets?**

**Montelukast sodium chewable tablets 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 chewable tablets:

- 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
- restlessness
- sleep walking
- suicidal thoughts and actions (including suicide)
- tremor
- trouble sleeping

• **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 chewable 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 with montelukast sodium chewable tablets 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 chewable tablets 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 chewable tablets. 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 chewable tablets?**

- Store montelukast sodium chewable tablets 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 chewable tablets in the container it comes in.
- Keep montelukast sodium chewable tablets in a dry place and away from light.

**General Information about the safe and effective use of montelukast sodium chewable tablets**

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

This leaflet summarizes information about montelukast sodium chewable tablets. If you would like more information, talk to your healthcare provider. You can ask your pharmacist or healthcare provider for information about montelukast sodium chewable tablets that is written for health professionals. For more information, call at 1-800-313-4623.

**What are the ingredients in montelukast sodium chewable tablets?**

**Active ingredient:** montelukast sodium, USP

**Inactive ingredients:** aspartame, colloidal silicon dioxide, croscarmellose sodium, hydroxypropyl cellulose, magnesium stearate, mannitol, microcrystalline cellulose, red ferric oxide, and strawberry flavor.

*Pediatric use information for patients ages 6 to 14 years of age for acute prevention of exercise-induced bronchoconstriction (EIB) is approved for Merck Sharp & Dohme Corp's montelukast tablet products. However, due to Merck Sharp & Dohme Corp's marketing exclusivity rights, this drug product is not labeled with that pediatric information.*

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Phenylketonurics: Contain phenylalanine (a component of aspartame), 1.34 and 1.68 mg per 4-mg and 5-mg Montelukast Sodium Chewable Tablets, respectively.

**Rx Only**

**Manufactured by:**

Jubilant Generics Limited  
Roorkee-247661, India

**Marketed by:**

Jubilant Cadista Pharmaceuticals Inc.  
Salisbury, MD-21801, USA


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