

MEDICATION GUIDE
SINGULAIR® (SING-u-lair)
(montelukast sodium)

tablets

chewable tablets

oral granules

What is the most important information I should know about SINGULAIR?

Serious mental health problems have happened in people taking SINGULAIR or even after treatment has stopped. This can happen in people with or without a history of mental health problems. Stop taking SINGULAIR 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:

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| <ul style="list-style-type: none">• agitation, including aggressive behavior or hostility• attention problems• bad or vivid dreams• depression• disorientation (confusion)• feeling anxious• irritability | <ul style="list-style-type: none">• hallucinations (seeing or hearing things that are not really there)• memory problems• obsessive-compulsive symptoms• restlessness• sleep walking• stuttering | <ul style="list-style-type: none">• suicidal thoughts and actions (including suicide)• tremor• trouble sleeping• uncontrolled muscle movements |
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What is SINGULAIR?

SINGULAIR 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). SINGULAIR does not contain a steroid.

SINGULAIR 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 SINGULAIR 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. SINGULAIR 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 SINGULAIR if you are allergic to any of its ingredients. See the end of this Medication Guide for a complete list of the ingredients in SINGULAIR.

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

- are allergic to aspirin.
- have phenylketonuria. SINGULAIR 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, SINGULAIR may not be right for you.
- are breastfeeding or plan to breastfeed. It is not known if SINGULAIR passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby while taking SINGULAIR.

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 SINGULAIR works, or SINGULAIR may affect how your other medicines work.

How should I take SINGULAIR?

For **anyone** who takes SINGULAIR:

- Read the detailed **Instructions for Use** that comes with SINGULAIR oral granules.
- Take SINGULAIR exactly as prescribed by your healthcare provider. Your healthcare provider will tell you how much SINGULAIR to take, and **when to take it**.
- Stop taking SINGULAIR and tell your healthcare provider right away if you or your child have any unusual changes in behavior or thinking.
- You can take SINGULAIR with food or without food. See the section "**How can I give SINGULAIR oral granules to my child?**" in the **Instructions for Use** for information about what foods and liquids can be taken with SINGULAIR oral granules.
- **If you or your child misses a dose of SINGULAIR, just take the next dose at your regular time.** Do not take 2 doses at the same time.
- If you take too much SINGULAIR, call your healthcare provider right away.

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

- Take SINGULAIR 1 time each day, in the evening. Continue to take SINGULAIR 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 SINGULAIR at least 2 hours before exercise.
- Always have your rescue inhaler medicine with you for asthma attacks.
- If you take SINGULAIR 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 SINGULAIR 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 SINGULAIR 1 time each day, at about the same time each day.

What should I avoid while taking SINGULAIR?

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 SINGULAIR.

What are the possible side effects of SINGULAIR?

SINGULAIR may cause serious side effects, including:

- See “What is the most important information I should know about SINGULAIR?”
- **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 SINGULAIR. 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 SINGULAIR 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 SINGULAIR. 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 SINGULAIR?

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

General information about the safe and effective use of SINGULAIR.

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

What are the ingredients in SINGULAIR?

Active ingredient: montelukast sodium

Inactive ingredients:

- **4-mg oral granules:** mannitol, hydroxypropyl cellulose, and magnesium stearate.
- **4-mg and 5-mg chewable tablets:** mannitol, microcrystalline cellulose, hydroxypropyl cellulose, red ferric oxide, croscarmellose sodium, cherry flavor, aspartame, and magnesium stearate.
- People with Phenylketonuria: **SINGULAIR 4-mg chewable tablets** contain 0.674 mg of phenylalanine and **SINGULAIR 5-mg chewable tablets** contain 0.842 mg of phenylalanine.
- **10-mg tablet:** microcrystalline cellulose, lactose monohydrate, croscarmellose sodium, hydroxypropyl cellulose, and magnesium stearate. The film coating contains: hydroxypropyl methylcellulose, hydroxypropyl cellulose, titanium dioxide, red ferric oxide, yellow ferric oxide, and carnauba wax.

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