

Patient Information
SINGULAIR® (SING-u-lair)
(montelukast sodium)
Tablets

SINGULAIR®
(montelukast sodium)
Chewable Tablets

SINGULAIR®
(montelukast sodium)
Oral Granules

Read the Patient Information Leaflet that comes with SINGULAIR® 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 SINGULAIR?

- SINGULAIR is a prescription medicine that blocks substances in the body called leukotrienes. This may help to improve symptoms of asthma and 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 get 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 (sneezing, stuffy nose, runny nose, itching of the nose). SINGULAIR 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 SINGULAIR?

Do not take SINGULAIR if you are allergic to any of its ingredients.

See the end of this leaflet for a complete list of the ingredients in SINGULAIR.

What should I tell my healthcare provider before taking SINGULAIR?

Before taking SINGULAIR, tell your healthcare provider if you:

- are allergic to aspirin

- have phenylketonuria. SINGULAIR chewable tablets contain aspartame, a source of phenylalanine
- have any other medical conditions
- are pregnant or plan to become pregnant. If you are pregnant or plan to become pregnant, SINGULAIR may not be right for you. If you become pregnant while taking SINGULAIR, talk to your healthcare provider about reporting your pregnancy to the Pregnancy Registry for SINGULAIR, or you can enroll in this registry by calling 1-800-986-8999.
- are breast-feeding or plan to breast-feed. 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 non-prescription 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:

- 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**.
- Do not stop taking SINGULAIR or change when you take it without talking with your healthcare provider.
- You can take SINGULAIR with food or without food. See the information below in the section "How should I give SINGULAIR oral granules to my child?" 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 doctor.

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.
- **Do not take SINGULAIR 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 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 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 SINGULAIR 1 time each day, at about the same time each day.

How should I give SINGULAIR oral granules to my child?

Give SINGULAIR oral granules to your child exactly as instructed by your healthcare provider.

Do not open the packet until ready to use.

SINGULAIR 4-mg 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 SINGULAIR 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 SINGULAIR 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 SINGULAIR?

The dose of SINGULAIR 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 4-mg chewable tablet or one packet of 4-mg oral granules.
- 6 to 14 years: one 5-mg chewable tablet.
- 15 years and older: one 10-mg tablet.

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.

- **Behavior and mood-related changes.** Tell your healthcare provider right away if you or your child have any of these symptoms while taking SINGULAIR:
 - agitation including aggressive behavior or hostility
 - bad or vivid dreams
 - depression
 - disorientation (confusion)
 - feeling anxious
 - hallucinations (seeing or hearing things that are not really there)
 - irritability
 - 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 SINGULAIR. This usually, but not always, 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 SINGULAIR 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 SINGULAIR 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
- diarrhea, heartburn, indigestion, inflammation of the pancreas, nausea, stomach or intestinal upset, vomiting
- hepatitis
- bruising, rash, severe skin reactions (erythema multiforme) that may occur without warning
- joint pain, muscle aches and muscle cramps
- 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 SINGULAIR. 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 SINGULAIR?

- Store SINGULAIR at 59°F to 86°F (15°C to 30°C).
- Keep SINGULAIR in the container it comes in.
- Keep SINGULAIR in a dry place and away from light.

General Information about the safe and effective use of SINGULAIR

Medicines are sometimes prescribed for purposes other than those mentioned in Patient Information Leaflets. 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. **Keep SINGULAIR and all medicines out of the reach of children.**

This leaflet summarizes information about SINGULAIR. If you would like more information, talk to your healthcare provider. You can ask your pharmacist or healthcare provider for information about SINGULAIR that is written for health professionals. For more information, go to www.singulair.com or call the Merck National Service Center at 1-800-NSC-Merck (1-800-672-6372).

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 (89.3 mg), 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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