



SINGULAIR® (Montelukast Sodium) Tablets and Chewable Tablets
Patient Information about
SINGULAIR® (SING-u-lair)

9094209

Generic name: montelukast (mon-te-LOO-kast) sodium

Read this information before you start taking SINGULAIR®. Also, read the leaflet each time you renew your prescription, in case anything has changed. This leaflet does not take the place of complete discussions with your doctor. You and your doctor should discuss SINGULAIR when you start taking your medicine and at regular checkups.

What is SINGULAIR®?

- Your doctor has prescribed SINGULAIR once a day for the long-term treatment of your (or your child's) asthma.
- SINGULAIR is a medicine called a leukotriene receptor antagonist. It works by blocking substances in the body called leukotrienes. Blocking leukotrienes improves asthma symptoms. SINGULAIR is not a steroid.
- SINGULAIR comes in 3 forms:
 1. A 10-mg tablet that you swallow whole (for adults and children above age 14).
 2. A 5-mg chewable tablet (for children ages 6-14).
 3. A 4-mg chewable tablet (for children ages 2-5).
- **SINGULAIR should NOT be used for the fast relief of asthma attacks.** If you get an asthma attack, you should follow the instructions your doctor gave you for treating asthma attacks.

What is asthma?

- Asthma is a continuing (chronic) lung disease. It cannot be cured, but it can be controlled.
- Symptoms of asthma include:
 - coughing
 - wheezing
 - chest tightness
- In some patients, symptoms worsen during the night or after exercise.

Who should not take SINGULAIR?

Patients with allergies to any components of SINGULAIR should not take SINGULAIR. The active ingredient in SINGULAIR is montelukast sodium. The inactive ingredients are listed at the end of this leaflet.

The safety and efficacy of SINGULAIR has not been established in children younger than age 2.

What should I tell my doctor before taking SINGULAIR?

Tell your doctor:

- If you are pregnant or plan to become pregnant. SINGULAIR may not be right for you.

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- If you are breast-feeding. SINGULAIR may be passed in your milk to your baby.
- About any medical problems or allergies you have now or have had.
- About all medicines that you are taking or plan to take, including those you can get without a prescription.

How should I take SINGULAIR?

- Take SINGULAIR once a day in the evening.
- Take SINGULAIR daily for as long as your doctor prescribes it, even if you have no symptoms.
- You may take SINGULAIR with or without food.
- Children who are prescribed SINGULAIR should take it under the supervision of an adult.
- If your symptoms get worse, or if you need to increase the use of your inhaled rescue medicine for asthma attacks, contact your doctor at once.
- **Do NOT take SINGULAIR to stop an asthma attack.** If an attack occurs, follow the instructions your doctor gave you for asthma attacks.
- It is very important that you continue taking your other asthma medicines unless your doctor tells you to stop. In addition, do not lower the dose of any of your asthma medicines unless you are told to do so by your doctor. Your doctor may decide to reduce the amount you use of your current asthma medicine.
- If your asthma is made worse by exercise, continue to use the medicines your doctor prescribed for you to use before exercise, unless your doctor tells you otherwise. Always have your inhaled rescue medicine for asthma attacks with you in case you need it.

The dose for adults and adolescents 15 years and older is one 10-mg tablet daily. The dose for children 6 to 14 years old is one 5-mg chewable tablet daily. The dose for children 2 to 5 years old is one 4-mg chewable tablet daily.

What should I avoid while taking SINGULAIR?

- If your asthma is made worse by aspirin, you should continue to avoid aspirin or other non-steroidal anti-inflammatory drugs, such as ibuprofen and naproxen.

What are the possible side effects of SINGULAIR?

The side effects of SINGULAIR are usually mild.

- The side effects in patients treated with SINGULAIR were similar in type and frequency to side effects in patients who were given a placebo (a pill containing no medication).

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The list below is **NOT** a complete list of side effects reported with SINGULAIR. Your doctor can discuss with you a more complete list of side effects. The most common side effects are listed below.

- tiredness
- fever
- abdominal (stomach) pain
- stomach or intestinal upset (gastroenteritis)
- heartburn
- dizziness
- headache
- rash
- cough
- flu
- stuffy nose

Less common side effects included the following

- allergic reactions including:
 - swelling of the face, lips, tongue, and/or throat, which may cause difficulty in breathing or swallowing
 - hives
 - itching
- bad/vivid dreams
- irritability
- restlessness
- insomnia
- seizure
- nausea
- vomiting
- dyspepsia
- diarrhea
- pancreatitis
- muscle aches and muscle cramps
- increased bleeding tendency
- bruising
- edema

Rarely, patients taking SINGULAIR have experienced a condition that includes a combination of certain symptoms that do not go away or that get worse. These symptoms may include:

- a flu-like illness
- rash
- a feeling of pins and needles or numbness of arms or legs
- severe inflammation (pain and swelling) of the sinuses (sinusitis)

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These have occurred usually, but not always, in patients who were taking oral corticosteroid pills for asthma and those corticosteroids were being slowly lowered or stopped. Although SINGULAIR has not been shown to cause this condition, you must tell your doctor right away if you develop one or more of these symptoms.

Remember, anytime you have a medical problem you think may be related to SINGULAIR, talk to your doctor.

Other Information

Do not share SINGULAIR with anyone else; it was prescribed only for you. Do not use it for a condition for which it was not prescribed.

Keep SINGULAIR and all medicines out of the reach of children.

Phenylketonurics: SINGULAIR 4-mg and 5-mg chewable tablets contain 0.674 and 0.842 mg phenylalanine, respectively.

This leaflet provides a summary of information about SINGULAIR. If you have any questions or concerns about either SINGULAIR or asthma, talk to your doctor. In addition, you can talk to your pharmacist or other health care provider. Your doctor or pharmacist can give you an additional leaflet that is written for health professionals.

Inactive ingredients:

4-mg and 5-mg chewable tablets: mannitol, microcrystalline cellulose, hydroxypropyl cellulose, red ferric oxide, croscarmellose sodium, cherry flavor, aspartame, and magnesium stearate.
10-mg tablet: microcrystalline cellulose, lactose monohydrate, croscarmellose sodium, hydroxypropyl cellulose, magnesium stearate, hydroxypropyl methylcellulose, titanium dioxide, red ferric oxide, yellow ferric oxide, and carnauba wax.

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