

coated tablets at 25°C (77°F), excursions permitted to 15-30°C (59-86°F) [see USP Controlled Room Temperature]. Protect from moisture and light. Store in original container. When product container is subdivided, repackage into a well-closed, light resistant container.

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## SUPPLEMENTAL PATIENT MATERIAL

### PATIENT INFORMATION

#### SINGULAIR® (SING-u-lair) Tablets, Chewable Tablets, and Oral Granules

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

Read this information before you start taking SINGULAIR®. Also, read the leaflet you get each time you refill SINGULAIR, since there may be new information in the leaflet since the last time you saw it. This leaflet does not take the place of talking with your doctor about your medical condition and/or your treatment.

#### What is SINGULAIR<sup>1</sup>?

- SINGULAIR is a medicine called a leukotriene receptor antagonist. It works by blocking substances in the body called leukotrienes. Blocking leukotrienes improves asthma and allergic rhinitis. SINGULAIR is not a steroid. Studies have shown that SINGULAIR does not affect the growth rate of children. (See the end of this leaflet for more information about asthma and allergic rhinitis.)

SINGULAIR is prescribed for the treatment of asthma, the prevention of exercise-induced asthma, and allergic rhinitis:

#### 1. Asthma.

SINGULAIR should be used for the long-term management of asthma in adults and children ages 12 months and older.

**Do not take SINGULAIR for the immediate relief of an asthma attack.** If you get an asthma attack, you should follow the instructions your doctor gave you for treating asthma attacks.

#### 2. Prevention of exercise-induced asthma.

SINGULAIR is used for the prevention of exercise-induced asthma in patients 15 years of age and older.

### 3. Allergic Rhinitis.

SINGULAIR is used to help control the symptoms of allergic rhinitis (sneezing, stuffy nose, runny nose, itching of the nose). SINGULAIR is used to treat seasonal allergic rhinitis (outdoor allergies that happen part of the year) in adults and children ages 2 years and older, and perennial allergic rhinitis (indoor allergies that happen all year) in adults and children ages 6 months and older.

### Who should not take SINGULAIR?

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

The active ingredient in SINGULAIR is montelukast sodium.

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

### What should I tell my doctor before I start taking SINGULAIR?

Tell your doctor about:

- **Pregnancy:** If you are pregnant or plan to become pregnant, SINGULAIR may not be right for you.
- **Breast-feeding:** If you are breast-feeding, SINGULAIR may be passed in your milk to your baby. You should consult your doctor before taking SINGULAIR if you are breast-feeding or intend to breast-feed.
- **Medical Problems or Allergies:** Talk about any medical problems or allergies you have now or had in the past.
- **Other Medicines:** Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, 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 adults and children 12 months of age and older with asthma:

- Take SINGULAIR once a day in the evening.
- Take SINGULAIR every day for as long as your doctor prescribes it, even if you have no asthma symptoms.
- You may take SINGULAIR with food or without food.
- If your asthma symptoms get worse, or if you need to increase the use of your inhaled rescue medicine for asthma attacks, call your doctor right away.
- **Do not take SINGULAIR for the immediate relief of an asthma attack.** If you get an asthma attack, you should follow the instructions your doctor gave you for treating asthma attacks.
- Always have your inhaled rescue medicine for asthma attacks with you.
- Do not stop taking or lower the dose of your other asthma medicines unless your doctor

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 inhaled rescue medicine for asthma attacks with you.
- If you are taking SINGULAIR daily for chronic asthma or allergic rhinitis, do not take an additional dose to prevent exercise-induced asthma. Speak to your doctor about your treatment of exercise-induced asthma.
- Do not take an additional dose of SINGULAIR within 24 hours of a previous dose.

**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 once a day, at about the same time each day.
- Take SINGULAIR every day for as long as your doctor prescribes it.
- You may take SINGULAIR with food or without food.

**How should I give SINGULAIR oral granules to my child?**

Do not open the packet until ready to use.

SINGULAIR 4-mg oral granules can be given:

- directly in the mouth;
- dissolved in 1 teaspoonful (5 mL) of cold or room temperature baby formula or breast milk;
- mixed with a spoonful of one of the following soft foods at cold or room temperature: applesauce, mashed carrots, rice, or ice cream.

Be sure that the entire dose is mixed with the food, baby formula, or breast milk and that the child is given the entire spoonful of the food, baby formula, or breast milk mixture right away (within 15 minutes).

**IMPORTANT:** Never store any oral granules mixed with food, baby formula, or breast milk for use at a later time. Throw away any unused portion.

**Do not put SINGULAIR oral granules in any liquid drink other than baby formula or breast milk.** However, your child may drink liquids after swallowing the SINGULAIR oral granules.

**What is the dose of SINGULAIR?**

**For asthma -Take once daily in the evening:**

- One 10-mg tablet for adults and adolescents 15 years of age and older,
- One 5-mg chewable tablet for children 6 to 14 years of age,
- One 4-mg chewable tablet or one packet of 4-mg oral granules for children 2 to 5 years

of age, or

- One packet of 4-mg oral granules for children 12 to 23 months of age.

**For exercise-induced asthma - Take at least 2 hours before exercise, but not more than once daily:**

- One 10-mg tablet for adults and adolescents 15 years of age and older.

**For allergic rhinitis -Take once daily at about the same time each day:**

- One 10-mg tablet for adults and adolescents 15 years of age and older,
- One 5-mg chewable tablet for children 6 to 14 years of age,
- One 4-mg chewable tablet for children 2 to 5 years of age, or
- One packet of 4-mg oral granules for children 2 to 5 years of age with seasonal allergic rhinitis, or for children 6 months to 5 years of age with perennial allergic rhinitis.

**What should I avoid while taking SINGULAIR?**

If you have asthma and if your asthma is made worse by aspirin, continue to avoid aspirin or other medicines called non-steroidal anti-inflammatory drugs while taking SINGULAIR.

**What are the possible side effects of SINGULAIR?**

The side effects of SINGULAIR are usually mild, and generally did not cause patients to stop taking their medicine. 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 medicine).

The most common side effects with SINGULAIR include:

- stomach pain
- stomach or intestinal upset
- heartburn
- tiredness
- fever
- stuffy nose
- cough
- flu
- upper respiratory infection
- dizziness
- headache
- rash

**Less common side effects that have happened with SINGULAIR include:**

- increased bleeding tendency
- allergic reactions [including swelling of the face, lips, tongue, and/or throat (which may cause trouble breathing or swallowing), hives and itching]
- **behavior and mood related changes** [agitation including aggressive behavior, bad/vivid dreams, depression, **feeling anxious**, hallucinations (seeing things that are not there), irritability, restlessness, **suicidal thoughts and actions (including suicide)**, tremor, trouble sleeping]
- palpitations
- drowsiness, pins and needles/numbness, seizures (convulsions or fits)
- diarrhea, indigestion, inflammation of the pancreas, nausea, vomiting
- hepatitis
- bruising
- joint pain, muscle aches and muscle cramps
- swelling

Rarely, asthmatic patients taking SINGULAIR have experienced a condition that includes certain symptoms that do not go away or that get worse. These occur usually, but not always, in patients who were taking steroid pills by mouth for asthma and those steroids 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 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)

These are not all the possible side effects of SINGULAIR. For more information ask your doctor or pharmacist.

Talk to your doctor if you think you have side effects from taking SINGULAIR.

### **General Information about the safe and effective use of SINGULAIR**

Medicines are sometimes prescribed for conditions that are not 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.**

Store SINGULAIR at 25°C (77°F). Protect from moisture and light. Store in original package.

This leaflet summarizes information about SINGULAIR. If you would like more information, talk to your doctor. You can ask your pharmacist or doctor for information about SINGULAIR that is written for health professionals.

### **What are the ingredients in SINGULAIR?**

Active ingredient: montelukast sodium

**SINGULAIR chewable tablets contain aspartame, a source of phenylalanine.**

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

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.
- 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.

### What is asthma?

Asthma is a continuing (chronic) inflammation of the bronchial passageways which are the tubes that carry air from outside the body to the lungs.

Symptoms of asthma include:

- coughing
- wheezing
- chest tightness
- shortness of breath

### What is exercise-induced asthma?

Exercise-induced asthma, more accurately called exercise-induced bronchoconstriction occurs when exercise triggers symptoms of asthma.

### What is allergic rhinitis?

- Seasonal allergic rhinitis, also known as hay fever, is triggered by outdoor allergens such as pollens from trees, grasses, and weeds.
- Perennial allergic rhinitis may occur year-round and is generally triggered by indoor allergens such as dust mites, animal dander, and/or mold spores.
- Symptoms of allergic rhinitis may include:
  - stuffy, runny, and/or itchy nose
  - sneezing

Rx only

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