

## IMPORTANT: PLEASE READ

### PART III: CONSUMER INFORMATION

# SINGULAIR®

montelukast tablets  
montelukast chewable tablets  
montelukast granules for oral use  
(as montelukast sodium)

This leaflet is part III of a three-part “Product Monograph” published when SINGULAIR® was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about SINGULAIR®. Contact your physician or pharmacist if you have any questions about the drug.

Please read this leaflet carefully before you or your child start to take this medicine, even if you have just refilled the prescription. Some of the information in the previous leaflet may have changed.

#### ABOUT THIS MEDICATION

##### **What the medication is used for:**

##### **Asthma (for adults, adolescents and children 2 to 14 years old):**

Your physician has prescribed SINGULAIR® to treat your asthma or your child’s asthma, including preventing your asthma symptoms during the day and night. When taken as prescribed, SINGULAIR® also prevents the narrowing of airways triggered by exercise.

SINGULAIR® can be used alone or together with other medications to help with the treatment and prevention of you or your child’s asthma. Your physician will decide which combination of medicines will work best for you or your child.

##### **Seasonal Allergic Rhinitis (for adults and adolescents 15 years and older):**

Your physician has prescribed SINGULAIR® to treat your seasonal allergies, including daytime and nighttime symptoms, including nasal congestion, runny nose, nasal itching, and sneezing; nasal congestion upon awakening; tearing, itchy, red, and puffy eyes.

##### **What it does:**

SINGULAIR® is a leukotriene receptor antagonist that blocks substances in your lungs called leukotrienes. Leukotrienes cause narrowing and swelling of airways in your lungs. Blocking leukotrienes improves asthma symptoms and helps prevent asthma attacks. Leukotrienes also can contribute to the development of allergy symptoms. Blocking leukotrienes improves

seasonal allergy symptoms (also known as hay fever or seasonal allergic rhinitis).

##### **When it should not be used:**

Do not take SINGULAIR® if you or your child are allergic to any of its ingredients. See what the non-medical ingredients are.

##### **What the medicinal ingredient is:**

montelukast sodium

##### **What the non-medical ingredients are:**

10 mg film-coated tablet: carnauba wax, croscarmellose sodium, hydroxypropyl cellulose, hydroxypropyl methylcellulose, lactose monohydrate (89.3 mg), magnesium stearate, microcrystalline cellulose, red ferric oxide, titanium dioxide, and yellow ferric oxide.

4 mg and 5 mg chewable tablet: aspartame, cherry flavor, croscarmellose sodium, hydroxypropyl cellulose, magnesium stearate, mannitol, and microcrystalline cellulose, and red ferric oxide.

4 mg packet of oral granules: hydroxypropyl cellulose, magnesium stearate and mannitol.

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

##### **What dosage forms it comes in:**

SINGULAIR® film-coated tablet 10 mg.

SINGULAIR® chewable tablet 4 mg, 5 mg.

SINGULAIR® oral granules 4 mg.

#### WARNINGS AND PRECAUTIONS

**SINGULAIR® is not for the treatment of acute asthma attacks.** If an attack occurs, you or your child should follow the instructions your physician has given you for that situation.

Behavior and mood-related changes have been reported in patients taking SINGULAIR®. If you or

your child experience these changes while taking SINGULAIR® (see "SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM"), tell your physician.

**BEFORE** using SINGULAIR®, tell your physician if you or your child:

- have phenylketonuria;
- suffer from liver problems;
- are using any other medicines;
- have or have had any medical problems or allergies.

You should immediately inform your doctor if you or your child start to have any:

- agitation, including aggressive behaviour or hostility (such as temper tantrums in children),
- suicidal thoughts and actions,
- anxiousness, depression (sad mood),
- disorientation (inability to know correct time, place or person), dream abnormalities, hallucinations (seeing or hearing things that are not there),
- insomnia, irritability, restlessness, sleep walking,
- tremors.

#### **Use in pregnancy**

Women who are pregnant or intend to become pregnant should consult their physician before taking SINGULAIR®.

#### **Use in breast-feeding**

It is not known if SINGULAIR® appears in breast milk. You should consult your physician before taking SINGULAIR® if you are breast-feeding or intend to breast-feed.

SINGULAIR® is not expected to affect your ability to drive a car or operate machinery. However, individual responses to medication may vary. Certain side effects (such as dizziness and drowsiness) that have been reported very rarely with SINGULAIR® may affect some patients' ability to drive or operate machinery.

If your or your child's asthma symptoms get worse, you should contact your physician immediately.

If your asthma is made worse by exercise, you should continue to use the medicines your physician has prescribed for you to use before exercise, unless your physician tells you otherwise. You should always have your inhaled rescue medicine for asthma attacks with you in case you need it.

If your asthma is made worse by acetylsalicylic acid (ASA) (e.g., Aspirin\*), you should continue to avoid ASA or other non-steroidal anti-inflammatory drugs.

## **INTERACTIONS WITH THIS MEDICATION**

In general, SINGULAIR® does not interfere with other medicines that you may be taking. However, some medicines may affect how SINGULAIR® works, or SINGULAIR® may affect how your other medicines work. It is important to tell your physician about all drugs that you are using or plan to use, including those obtained without a prescription.

## **PROPER USE OF THIS MEDICATION**

### **Usual dose:**

#### **Asthma (for adults, adolescents and children 2 to 14 years old):**

Take SINGULAIR® once a day in the evening with or without food, as your physician has prescribed.

SINGULAIR® oral granules for children 2 to 5 years old can be given either:

- directly in the mouth;  
OR
- all contents mixed with a spoonful of cold or room temperature soft food (for example, applesauce), taking care to see that the entire dose is mixed with the food.

Do not open the packet until ready to use.

Be sure the child is given the entire spoonful of the oral granule/food mixture immediately (within 15 minutes). **IMPORTANT:** Never store any oral granule/food mixture for use at a later time.

SINGULAIR® oral granules are not intended to be dissolved in liquid. However, your child may take liquids after swallowing the SINGULAIR® oral granules.

Take SINGULAIR® daily for as long as your physician prescribes it in order to maintain control of your or your child's asthma. SINGULAIR® can treat your or your child's asthma only if you or your child continue to take it.

It is important that you or your child **continue taking SINGULAIR® daily as prescribed by your physician, even when you or your child has no symptoms or if you or your child has an asthma attack.**

If you are taking other medications along with SINGULAIR® your physician will instruct you how and when to take each medication. Your physician will increase or decrease the doses of these medications as needed.

**Seasonal Allergic Rhinitis (for adults and adolescents 15 years and older):**

Take SINGULAIR® once a day in the evening with or without food, as your physician has prescribed.

Remember that your physician has prescribed this medicine only for you or your child. Never give it to anyone else.

Follow up with your physician to ensure your continued health and safety.

**Overdose:**

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

**Missed Dose:**

Try to take SINGULAIR® as prescribed. However, if you miss a dose, just resume the usual schedule of one tablet or packet once daily.

**SIDE EFFECTS AND WHAT TO DO ABOUT THEM**

Any medicine may have unintended or undesirable effects, so-called side effects. SINGULAIR® is generally well-tolerated. The most common side effects reported were;

- abdominal pain
- headache
- thirst
- diarrhea
- hyperactivity
- asthma
- scaly and itchy skin
- rash

These were usually mild.

Additionally, the following have been reported:

- upper respiratory tract infection (common cold)
- feeling anxious, irritability, restlessness, sleep walking, sleep disorders including dream abnormalities and insomnia
- dizziness, drowsiness, pins and needles/numbness
- nose bleed
- joint pain, muscle aches and muscle cramps
- tender red lumps under the skin, most commonly on your shins
- weakness/tiredness, fatigue
- swelling
- fever

Tell your physician or pharmacist if you develop any of the above symptoms, any unusual symptom, or if any known symptom continues or worsens.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptoms / Effects		Talk with your physician or pharmacist		Stop taking drug and seek immediate emergency medical attention
		Only if severe	In all cases	
Rare	symptoms of allergic reactions such as swelling of the face, lips, tongue, and/or throat (which may cause difficulty in breathing or swallowing), hives, rash, and itching			✓
Very Rare	symptoms of liver problems: nausea, vomiting, fatigue, jaundice (yellowing of the skin and eyes), dark urine, flu-like symptoms, loss of appetite, and pain in your abdomen			✓
	increased bleeding tendency, bruising	✓		
	severe skin reactions (erythema multiforme) that may occur without warning	✓		
	behavior and mood related changes [agitation including aggressive behavior or hostility (such as temper tantrums in children)]	✓		
	depression	✓		
	disorientation (inability to know correct time, place or person)	✓		
	suicidal thoughts and actions			✓
	tremor	✓		
	hallucinations (seeing or hearing things that are not there)	✓		
	seizure (convulsions or fits)			✓
	palpitations (heart skips a beat)	✓		
	Churg-Strauss syndrome: a flu-like illness, rash, pins and needles or numbness of arms or legs, joint pain and severe sinusitis			✓

***This is not a complete list of side effects. For any unexpected effects while taking SINGULAIR®, contact your physician or pharmacist.***

## HOW TO STORE IT

Store at room temperature (15°C–30°C) in a dry place.

**Keep all medicines safely away from children.**

### **REPORTING SUSPECTED SIDE EFFECTS**

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at [www.healthcanada.gc.ca/medeffect](http://www.healthcanada.gc.ca/medeffect)
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
  - Fax toll-free to 1-866-678-6789, or
  - Mail to: Canada Vigilance Program  
Health Canada  
Postal Locator 0701E  
Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at [www.healthcanada.gc.ca/medeffect](http://www.healthcanada.gc.ca/medeffect)

**or at Merck Canada Inc.** by one of the following 2 ways:

- Call toll-free at 1-800-567-2594
- Complete a Canada Vigilance Reporting Form and:
  - Fax toll-free to 1-800-369-3090, or
  - Mail to: Merck Canada Inc.  
Pharmacovigilance  
P.O. Box 1005  
Pointe-Claire–Dorval, QC H9R 4P8

*NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program or Merck do not provide medical advice.*

## MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at: [www.merck.ca](http://www.merck.ca) or by contacting the sponsor, Merck Canada Inc., at: 1-800-567-2594

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