

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.

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.

Exercise-induced bronchoconstriction (for adults, adolescents and children 2 years and older with asthma): When taken as prescribed, SINGULAIR[®] also prevents the narrowing of airways triggered by exercise.

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-medicinal ingredients are.

What the medicinal ingredient is:

montelukast sodium

What the non-medicinal 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

Serious Warnings and Precautions

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:

- agitation, including aggressive behavior or hostility
- attention problems
- bad or vivid dreams
- depression
- disorientation (confusion)
- feeling anxious
- irritability
- hallucinations (seeing or hearing things that are not really there)
- memory problems
- obsessive-compulsive symptoms
- restlessness
- sleep walking
- stuttering
- suicidal thoughts and actions (including suicide)
- tremor
- trouble sleeping
- uncontrolled muscle movements

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.

Serious 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 behavior 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,
- disturbance in attention, memory problems,
- stuttering.

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 15 years and older:

Take one 10 mg SINGULAIR® tablet once a day in the evening with or without food, as your physician has prescribed.

Patients 6 to 14 years of age:

Take one 5 mg SINGULAIR® chewable tablet once a day in the evening with or without food, as your physician has prescribed.

Patients 2 to 5 years old:

Patients can take one 4 mg SINGULAIR® chewable tablet once a day in the evening with or without food, as your physician has prescribed.

Alternatively, patients can use SINGULAIR® 4 mg oral granules once a day in the evening either:

- directly in the mouth;

OR

- by mixing all contents 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 one 10 mg SINGULAIR® tablet 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 take the next dose when it is due. Do not take two doses at the same time.

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
- uncontrolled muscle movements
- 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
- bedwetting in children

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			
sleep disorders including dream abnormalities and insomnia	✓		
sleep walking		✓	
disturbance in attention, memory problems		✓	
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, low blood platelet count		✓	
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), irritability, restlessness, obsessive-compulsive symptoms, anxiousness, depression (sad mood)		✓	
disorientation (inability to know correct time, place or person)		✓	
suicidal thoughts and actions			✓
stuttering		✓	
tremor		✓	
hallucinations (seeing or hearing things that are not there)		✓	
seizure (convulsions or fits)			✓
palpitations (heart skips a beat)	✓		
eosinophilic granulomatosis with polyangiitis (EGPA), formerly known as Churg-Strauss syndrome: a flu-like illness, rash, pins and needles or numbness of arms or legs, joint pain and severe sinusitis			✓
swelling (inflammation) of the lungs: breathing problems that continue to get worse			✓

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 the 10 mg film-coated tablets, and the 4 mg and 5 mg chewable tablets at room temperature (15°C–30°C). Protect from moisture and light.

Store the 4 mg oral granules at room temperature (15°C–30°C), in the original package.

Keep all medicines safely away from children.

REPORTING SIDE EFFECTS

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

If you want more information about SINGULAIR®:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Consumer Information by visiting the [Health Canada website \(https://health-products.canada.ca/dpd-bdpp/index-eng.jsp\)](https://health-products.canada.ca/dpd-bdpp/index-eng.jsp), www.organon.ca or by calling 1-844-820-5468.

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