

PART III: CONSUMER INFORMATION

**Pr MONTELUKAST
Montelukast Sodium tablets
(10mg)
Montelukast Sodium chewable tablets
(4mg and 5mg)**

This leaflet is part III of a three-part "Product Monograph" published when MONTELUKAST was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about MONTELUKAST. 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 MONTELUKAST to treat your asthma or your child's asthma, including preventing your asthma symptoms during the day and night.

MONTELUKAST 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 MONTELUKAST to treat your seasonal allergies, including daytime and night-time 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, MONTELUKAST also prevents the narrowing of airways triggered by exercise.

What it does:

MONTELUKAST 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 MONTELUKAST 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 (as montelukast sodium)

What the non-medicinal ingredients are:

10 mg film-coated tablet: cellulose microcrystalline, croscarmellose sodium, hydroxypropyl cellulose, hypromellose, iron oxide red, iron oxide yellow, lactose monohydrate, macrogol, magnesium stearate, titanium dioxide.

4 mg and 5 mg chewable tablet: aspartame, cellulose hydroxypropyl, cellulose microcrystalline, croscarmellose sodium, red ferric oxide, cherry flavour (acacia gum, allura red, fatty acids, flavouring substances, maize maltodextrin, silicon dioxide, sugar), magnesium stearate, mannitol.

Phenylketonurics: MONTELUKAST 4 mg and 5 mg chewable tablets contain 0.48 and 0.60 mg phenylalanine, respectively.

What dosage forms it comes in:

MONTELUKAST film-coated tablet 10 mg

MONTELUKAST chewable tablet 4 mg and 5 mg.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

Serious mental health problems have happened in people taking MONTELUKAST or even after treatment has stopped. This can happen in people with or without a history of mental health problems. Stop taking MONTELUKAST 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

MONTELUKAST 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 MONTELUKAST. If you or your child experience these changes while taking MONTELUKAST (see "SERIOUS

SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM"), tell your physician.

BEFORE using MONTELUKAST, 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 MONTELUKAST.

Use in breast-feeding

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

MONTELUKAST 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 montelukast sodium may affect some patients' ability to drive or operate machinery.

If you 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), you should continue to avoid ASA or other non-steroidal anti-inflammatory drugs.

INTERACTIONS WITH THIS MEDICATION

In general, MONTELUKAST does not interfere with other medicines that you may be taking. However, some medicines may affect how MONTELUKAST works, or MONTELUKAST 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 MONTELUKAST 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 MONTELUKAST 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 MONTELUKAST chewable tablet once a day in the evening with or without food, as your physician has prescribed.

Take MONTELUKAST daily for as long as your physician prescribes it in order to maintain control of your or your child's asthma. MONTELUKAST 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 MONTELUKAST 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 MONTELUKAST 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 MONTELUKAST 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 MONTELUKAST 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. Montelukast sodium 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

Symptom/effect		Talk with your doctor 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	✓		

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Symptom/effect	Talk with your doctor or pharmacist		Stop taking drug and seek immediate emergency medical attention
	Only if severe	In all cases	
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)		✓	

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Symptom/effect	Talk with your doctor or pharmacist		Stop taking drug and seek immediate emergency medical attention
	Only if severe	In all cases	
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 MONTELUKAST, contact your physician or pharmacist.

HOW TO STORE IT

Store at room temperature (15°C - 30°C), protect from moisture and light. **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 (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) 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 MONTELUKAST:

- 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>) the manufacturer's website (www.sivem.ca), or by calling the manufacturer, at 1-855-788-3153.

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