

PART III: CONSUMER INFORMATION**Pr MONTELUKAST**

montelukast (as montelukast sodium) Tablets

montelukast (as montelukast sodium)
Chewable Tablets

This leaflet is part III of a three-part "Product Monograph" published when MONTELUKAST (montelukast sodium) were 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. When taken as prescribed, MONTELUKAST also prevents the narrowing of airways triggered by exercise.

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 nighttime symptoms, including nasal congestion, runny nose, nasal itching, and sneezing; nasal congestion upon awakening; tearing, itchy, red, and puffy eyes.

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 sodium

What the non-medicinal ingredients are:**MONTELUKAST**

10 mg film-coated tablet: croscarmellose sodium, hydroxypropyl cellulose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, sodium lauryl sulfate. The film-coating consists of: black iron oxide, hydroxypropyl cellulose, hypromellose, polyethylene glycol, red iron oxide, talc, titanium dioxide and yellow iron oxide.

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

Phenylketonurics: Phenylalanine is a component of aspartame. MONTELUKAST 4 mg and 5 mg chewable tablets contain 1.20 and 1.50 mg aspartame, respectively.

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

Film-coated tablet: 10 mg.

Chewable tablet: 4 mg and 5 mg

WARNINGS AND PRECAUTIONS

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.

Behavior and mood-related changes have been reported in patients taking MONTELUKAST. If you or your child experience these changes while taking the drug (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 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,
- disturbance in attention, memory impairment.

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 appears in breast milk. You should consult your physician before taking MONTELUKAST if you are breast-feeding or intend to breast-feed.

MONTELUKAST are 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 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, MONTELUKAST do not interfere with other medicines that you or your child 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 or your child 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 MONTELUKAST 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 MONTELUKAST 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, 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. MONTELUKAST 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, disturbance in attention, memory impairment, 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
- 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			✓
	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			✓
Very Rare	increased bleeding tendency, bruising, low blood platelet count		✓	
	severe skin reactions (erythema multiforme) that may occur without warning	✓		
	behaviour and mood related changes [agitation including aggressive	✓		

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Symptoms / Effects	Talk with your physician or pharmacist		Stop taking drug and seek immediate emergency medical attention
	Only if severe	In all cases	
behaviour 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			✓
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) protected from moisture and light.

Keep all medicines safely away from children.

REPORTING SIDE EFFECTS

You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

3 ways to report:

- Online at www.healthcanada.gc.ca/medeffect;
- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form and sending it by:
 - Fax to 1-866-678-6789 (toll-free), or
 - Mail to: Canada Vigilance Program
Health Canada, Postal Locator 0701E
Ottawa, ON
K1A 0K9Postage paid labels and the Consumer Side Effect Reporting Form are available at www.healthcanada.gc.ca/medeffect.

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

This document plus the full product monograph, prepared for health professionals, can be obtained by contacting Pro Doc Ltée at 1-800-361-8559, www.prodoc.qc.ca or info@prodoc.qc.ca.

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