

**PART III: CONSUMER INFORMATION**

**Pr APO-MONTELUKAST**

montelukast (as montelukast sodium)

10 mg tablets

Apotex Standard

This leaflet is part III of a three-part "Product Monograph" published when APO-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 APO-MONTELUKAST. Contact your physician or pharmacist if you have any questions about the drug.

Please read this leaflet carefully before you 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 and adolescents 15 years and older):**

Your physician has prescribed APO-MONTELUKAST to treat your asthma, including preventing your asthma symptoms during the day and night. When taken as prescribed, APO-MONTELUKAST also prevents the narrowing of airways triggered by exercise.

APO-MONTELUKAST can be used alone or together with other medications to help with the treatment and prevention of your asthma. Your physician will decide which combination of medicines will work best for you.

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

Your physician has prescribed APO-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:**

APO-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 APO-MONTELUKAST if you 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: Lactose Monohydrate (Pharmatose 200 M), Cellulose, Microcrystalline (Avicel PH 101), Croscarmellose Sodium (AC-Di-Sol<sup>®</sup>-Type SD-711), Hydroxy Propyl Cellulose (Klucel- LF), Magnesium Stearate (Ligamed MF-2-V), Hydroxy Propyl Cellulose, HPMC 2910/ Hypromellose 6cP, Titanium Dioxide, Iron Oxide Yellow, Carnauba Wax & Iron Oxide Red (NF).

**What dosage forms it comes in:**

APO-MONTELUKAST film-coated tablet 10 mg.

**WARNINGS AND PRECAUTIONS**

**APO-MONTELUKAST is not for the treatment of acute asthma attacks.**

If an attack occurs, you should follow the instructions your physician has given you for that situation.

Behavior and mood-related changes have been reported in patients taking montelukast sodium. If you experience these changes while taking APO-MONTELUKAST (see "SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM"), tell your physician.

**BEFORE** using APO-MONTELUKAST, tell your physician if you:

- 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 start to have any:

## IMPORTANT: PLEASE READ

- 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 impairment

### Use in pregnancy

Women who are pregnant or intend to become pregnant should consult their physician before taking APO-MONTELUKAST.

### Use in breast-feeding

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

APO-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 your 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, APO-MONTELUKAST does not interfere with other medicines that you may be taking. However, some medicines may affect how APO-MONTELUKAST works, or APO-

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 and adolescents 15 years and older):

Take APO-MONTELUKAST once a day in the evening with or without food, as your physician has prescribed.

Take APO-MONTELUKAST daily for as long as your physician prescribes it in order to maintain control of your asthma. APO-MONTELUKAST can treat your asthma only if you continue to take it.

It is important that you **continue taking APO-MONTELUKAST daily as prescribed by your physician, even when you have no symptoms or if you have an asthma attack.**

If you are taking other medications along with APO-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 APO-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. 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 APO-MONTELUKAST as prescribed. However, if you miss a dose, just resume the usual schedule of one tablet or packet once daily.

**IMPORTANT: PLEASE READ**

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

Any medicine may have unintended or undesirable effects, so-called side effects. APO-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, 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 to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>Rare</b>			
symptoms of allergic reactions			

**SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM**

Symptoms / Effects	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
such as swelling of the face, lips, tongue, and/or throat (which may cause difficulty in breathing or swallowing), hives, rash, and itching			√
<b>Very Rare</b>			
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)]		√	
depression		√	
disorientation (inability to know correct time, place or person)		√	
suicidal thoughts and actions			√
tremor		√	
hallucinations (seeing or hearing things that are not		√	

**SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM**

Symptoms / Effects	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
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 APO-MONTELUKAST, contact your physician or pharmacist.*

**HOW TO STORE IT**

Store at room temperature (15°C to 30°C).

**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 APO-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://www.canada.ca/en/health-canada.html>). Find the Consumer Information on the manufacturer's website (<http://www.apotex.ca/products>) or by calling 1-800-667-4708

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