

PART III: CONSUMER INFORMATION

Pr ACCOLATE[®]
zafirlukast tablets

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

ABOUT THIS MEDICATION

REMEMBER: This medicine was prescribed only for **YOU**. Only a doctor knows who can use it safely. Never give it to someone else. It may harm them, even if their symptoms are the same as yours.

WHAT THE MEDICATION IS USED FOR:

ACCOLATE is used to control asthma symptoms, and prevent asthma from getting worse in adults and children 12 years and older.

ACCOLATE should be used as an add-on therapy to your current treatment for asthma (such as fast-acting relief medications or inhaled corticosteroids).

WHAT IT DOES:

ACCOLATE is a leukotriene receptor antagonist that blocks substances called leukotrienes. Leukotrienes cause a narrowing and swelling of airways in your lungs which results in asthma symptoms. Blocking leukotrienes improves asthma symptoms and helps prevent asthma attacks.

Improvement in your asthma symptoms should occur within one week of starting treatment with ACCOLATE. The effects of ACCOLATE last for up to 12 hours. Regular ACCOLATE use will help to control your symptoms.

WHEN IT SHOULD NOT BE USED:

You should not take ACCOLATE if you:

- Are allergic to zafirlukast or any of the ingredients in ACCOLATE tablets.
- Have problems with your liver.

WHAT THE MEDICINAL INGREDIENT IS:

zafirlukast

WHAT THE NONMEDICINAL INGREDIENTS ARE:

Film coated tablet: croscarmellose sodium, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, povidone, and titanium dioxide.

WHAT DOSAGE FORMS IT COMES IN:

Tablet: 20 mg

WARNINGS AND PRECAUTIONS

ACCOLATE is not for the treatment of asthma attacks.

ACCOLATE does not act quickly enough to be used as a relief medication. If you get a sudden attack of wheezing and breathlessness between doses of ACCOLATE, you should take one or two puffs from a fast-acting relief medication (e.g., terbutaline, salbutamol) that your doctor has given you.

Remember, if you have an attack that does not get better when you take the relief medication you should see your doctor right away. You may need emergency treatment.

You should tell your doctor as soon as possible if you:

- are getting more attacks of wheezing, breathlessness or chest tightness,
- are using an increasing amount of fast-acting relief medication,
- start to wake up at night with chest tightness, wheezing or shortness of breath.

Before using ACCOLATE, tell your doctor if:

- you suffer from liver problems;
- you are taking warfarin (blood thinner);
- you are pregnant, planning to become pregnant or breastfeeding.

If you go into hospital, let the medical staff know that you are taking ACCOLATE.

INTERACTIONS WITH THIS MEDICATION

BEFORE you use ACCOLATE, make sure your doctor knows about **all** other medicines you are taking (**including non-prescription or over the counter products**), especially blood thinners (warfarin), allergy medications, acetylsalicylic acid (Aspirin), antibiotics, and theophylline. This list is not complete and ACCOLATE may also interact with other medications.

PROPER USE OF THIS MEDICATION

Follow your doctor's instructions about when and how to take your tablets. Please **READ THE LABEL** on the package. Ask your doctor or pharmacist if you are not sure.

DO NOT stop taking or lower the amount of any other asthma medications you are taking while taking ACCOLATE unless instructed by your doctor.

USUAL DOSE:

For patients 12 years of age and older, the usual treatment with ACCOLATE is 20 mg (one tablet) twice daily (in the morning and evening).

- Swallow each tablet whole with a full glass of water.
- Do not take your tablet(s) with a meal (at least 1 hour before or 2 hours after meals).
- Try to take your medicine at the same times each day.

Using ACCOLATE twice a day, regularly, is very important. Your tablets come in blister cards of 10. All tablets in each card are the same. To help you remember your schedule, blisters are labelled with 2 spots per day, (a.m. and p.m.). You can start ACCOLATE at any time. When starting a card, note the day and time you took the tablet. Take your next tablet approximately 12 hours later, punching out the tablet that corresponds with the time (a.m. or p.m.). As you get to the end of your last card, call your pharmacist for a refill, preferably before using the last four tablets.

REMEMBER: ACCOLATE should be taken regularly. Do not stop taking your tablets even if you are feeling well, unless your doctor tells you.

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:

If you forget to take a dose, do not worry. Take another tablet as soon as you remember. **BUT** if it is near the time for the next dose, wait until this dose is due. Then go on as before. **Do not take a double dose.**

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like any medication, ACCOLATE may cause side effects in some people. Tell your doctor or pharmacist if any of the following side effects bothers you, continues or gets worse:

The common side effects reported were:

- Nausea, vomiting, diarrhoea, stomach pain
- Muscle pain
- Rash
- Headache
- Infections (including respiratory infections)

Less common side effects reported were:

- Feelings of discomfort or of being unwell
- Swelling
- Blisters
- Pain in the joints
- Itching
- Sleeping difficulties (insomnia)

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	
Uncommon (frequency of 1 to 10 in 1,000 patients)			
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			X
Rare (frequency of 1 to 10 in 10,000 patients)			
Inflammation of the liver (hepatitis).—Symptoms may include: nausea, vomiting, tired or lack of energy, flu-like symptoms, loss of appetite, itching, pain on the right side of your stomach (just below your ribs), yellowing of the skin and eyes (jaundice), dark urine, and discoloured and/or pale stools.			X
Increased bleeding tendency or bruising		X	
Churg-Strauss syndromes: a flu-like illness, rash, pins and needles or numbness of arms or legs, joint pain and severe sinusitis and worsening lung or breathing problems.			X
Very Rare (frequency of less than 1 in 10,000)			

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	
Severe liver injury, including liver failure (which may result in liver transplantation or death). Symptoms may include: nausea, vomiting, tired or lack of energy, flu-like symptoms, loss of appetite, itching, pain on the right side of your stomach (just below your ribs), yellowing of the skin and eyes (jaundice), dark urine, and discoloured and/or pale stools.			X
Low white blood cell count. Symptoms may include: an increased risk of infection, as shown by a sudden fever, sore throat, chills, or mouth ulcers.			X

This is not a complete list of side effects. For any unexpected effects while taking ACCOLATE, contact your doctor or pharmacist.

HOW TO STORE IT

Keep out of reach and sight of children.

You should store your tablets between 15 and 30°C (room temperature). Keep your tablets in the original package.

If your doctor decides to stop your treatment, return your tablets to the pharmacist for disposal.

Do not take your tablets after the expiry date on the package.

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
- 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, Ontario
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.

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

MORE INFORMATION

This document plus the full Product Monograph, prepared for health professionals can be found at: www.astrazeneca.ca, or by contacting the sponsor, AstraZeneca Canada Inc. at: Customer Inquiries – 1 (800) 668-6000, Renseignements – 1 (800) 461-3787.

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