

IMPORTANT: PLEASE READ

PART III: CONSUMER INFORMATION

APO-LORATADINE Loratadine Tablets USP 10 mg

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

ABOUT THIS MEDICATION

What the medication is used for:

APO-LORATADINE Tablets provide:

- fast relief from symptoms of allergies, including sneezing, runny nose and itchy nose, as well as itchy watery red burning eyes, caused by exposure to seasonal allergens (trees, grass, and ragweed pollen) and perennial (year round) allergens (dust mites, animal dander and moulds).
- fast relief of allergic skin conditions, such as skin itch and hives.

What it does:

APO-LORATADINE contains a long-acting antihistamine, which blocks the action of histamine and relieves allergy symptoms. Histamine is a chemical released by the immune system – the body's defence against invading substances – when the body is affected by substances that you are allergic to (allergens).

Most people will feel relief of allergy symptoms within 2 hours of taking the medication.

Symptom relief will be maintained for 24 hours.

APO-LORATADINE does not cause drowsiness. It lets you stay alert and focused while relieving allergy symptoms.

When it should not be used:

APO-LORATADINE should not be used:

- if you are allergic to loratadine or to any of the other product ingredients (see What the important non-medicinal ingredients are).
- if you are pregnant or nursing.

What- the medicinal ingredient is:

Loratadine

What the important nonmedicinal ingredients are:

colloidal silicon dioxide, croscarmellose sodium, lactose monohydrate, magnesium stearate, and microcrystalline cellulose.

What dosage forms it comes in:

Tablets, 10mg

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

- If you have severe liver disease, take 5 mg once daily or 10 mg every other day.

BEFORE you use APO-LORATADINE talk to your doctor or pharmacist if:

- you have severe liver disease

Stop taking APO-LORATADINE 48 hours prior to any skin testing procedures.

INTERACTIONS WITH THIS MEDICATION

APO-LORATADINE may interact with drugs known to reduce liver metabolism.

If you are taking any medication, it is important to ask your physician or pharmacist before taking APO-LORATADINE.

Alcohol has not been found to interact with APO-LORATADINE.

PROPER USE OF THIS MEDICATION

Usual dose:

APO-LORATADINE Tablets: Adults and adolescents (12 years of age and older): One tablet daily, with water.

Adults and adolescents (over 12 years of age) can take this medication for up to 6 months.

Do not give APO-LORATADINE to children between 2 and 12 years of age for longer than 14 days, unless recommended by your doctor.

Overdose:

If you think you have taken too much APO-LORATADINE, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you miss taking your dose on time, do not worry; take your dose when you remember. Do not

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exceed more than one dose in 24 hours.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Along with its desired effects, APO-LORATADINE may cause undesirable effects.

Mild side effects that may occur include fatigue, headache, dry mouth, sedation, stomach and digestive discomfort such as gastritis (inflammation of the stomach) and nausea.

Uncommon side effects include: Increase in appetite, coughing, and dizziness. Rarely, you may experience allergic reactions to the medication that may appear as a rash, swelling or difficulty in breathing. Additionally, hair loss, abnormal liver function, and abnormally fast heart rate or heart palpitations may occur rarely. Convulsions and seizures may occur very rarely.

Uncommon side effects in children include nervousness and nervous ticks as well as side effects involving the stomach or intestines.

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

Symptom / effect		Talk to your doctor or pharmacist		Stop taking drug and get immediate medical help
		Only if severe	In all cases	
Common	Stomach discomfort - i.e. gastritis (inflammation of the stomach)			✓
Uncommon	Allergic reaction (rash, swelling, difficulty in breathing)			✓
Rare	Fast heart rate or heart palpitations			✓
	Liver dysfunction			✓

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

HOW TO STORE IT

Store between 15°C and 30°C. Protect from exposure to excessive moisture.

Keep in safe place out of reach and sight of 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-LORATADINE:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website <http://www.apotex.ca/products>, or by calling 1-800-667-4708.

This leaflet was prepared by Apotex Inc., Toronto, Ontario, M9L 1T9.

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