

**READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR
MEDICINE
PATIENT MEDICATION INFORMATION**

Pr APO-NADOLOL

Nadolol Tablets USP

Read this carefully before you start taking **AP0-NADOLOL**. Read it again every time you get a refill. This leaflet is a summary. It will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment. Ask whether there is any new information about **AP0-NADOLOL**.

What is APO-NADOLOL used for?

AP0-NADOLOL is used to treat high blood pressure (also known as hypertension) in adults. It can be used alone or with other medicines.

AP0-NADOLOL is also used to prevent chest pain (also known as angina) in adults.

How does APO-NADOLOL work?

AP0-NADOLOL belongs to a group of drugs called “beta blockers.”

- It makes your heart beat more slowly and less forcefully.
- It lowers your blood pressure by relaxing your blood vessels so that your blood flows more easily.

This medicine does not cure your disease but helps to control it.

What are the ingredients in APO-NADOLOL?

Medicinal ingredients: nadolol.

Non-medicinal ingredients: lactose monohydrate, microcrystalline cellulose, magnesium stearate, croscarmellose sodium, colloidal silicon dioxide

AP0-NADOLOL comes in the following dosage forms:

Tablets: 40 mg (white), 80 mg (white), 160 mg (blue)

Do not use APO-NADOLOL if you:

- Are allergic to nadolol or any of the other ingredients in **AP0-NADOLOL**.
- Have heart failure and you notice that your symptoms are getting worse. For example you feel more tired, are out of breath more often, or have swelling of the ankles.
- Have severe heart damage and your heart is not able to pump enough blood to meet

your body's needs.

- Have a slow or irregular heart beat.
- Have an abnormal heart rate or rhythm.
- Have a problem with your heart's electrical conduction (that causes you to have chest pain, difficulty breathing, nausea, fatigue and fainting).
- Have severe liver disease.
- Have serious problems with blood flow in your feet and legs (peripheral artery disease).
- Have one of the following rare hereditary diseases:
 - Galactose intolerance
 - Lapp lactase deficiency
 - Glucose-galactose malabsorption
- Are 18 years and younger.

To make sure you take the drug properly and don't have side effects, talk to your healthcare professional before you take APO-NADOLOL. Talk about any health conditions or problems you may have, including if you:

- Have asthma or other lung problems (like bronchitis or emphysema).
- Have a history of heart problems.
- Have a history of fainting.
- Have diabetes and take medicine to control your blood sugar or have low blood sugar (hypoglycemia).
- Have a condition called pheochromocytoma (a tumour of the adrenal gland).
- Have thyroid problems.
- Have liver or kidney problems.
- Have had allergic reactions or have allergies.
- Are pregnant or trying to become pregnant. **APO-NADOLOL** is not usually recommended for use during pregnancy. Your doctor will consider the benefit to you versus the risk to your unborn baby.
- Are breastfeeding. You should not breastfeed while using **APO-NADOLOL**.
- Are scheduled for surgery and will be given an anesthetic.
- Develop a skin rash while taking **APO-NADOLOL**.

Other warnings you should know about:

Do not stop taking **APO-NADOLOL** suddenly. This could cause chest pain or a heart attack. If your doctor decides that you should stop taking **APO-NADOLOL**, your dose may be reduced so that you need to use less and less before you stop the medication completely.

Driving and using machines: Before doing tasks that require special attention, wait until you know how you respond to **APO-NADOLOL**.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following drugs may interact with APO-NADOLOL:

- Drugs used for lowering blood pressure:
 - ACE inhibitors (such as lisinopril)
 - Calcium channel blockers (such as verapamil and diltiazem)
 - Clonidine
- Drugs used to treat depression and mood disorders (such as fluoxetine, paroxetine, and venlafaxine)
- Anesthetic drugs used during surgery (such as ether and cyclopropane)
- Drugs used to treat diabetes such as insulin and oral medicines. You could become less aware of the symptoms of low blood sugar.
- Drugs used to treat heartburn and ulcers (such as cimetidine)
- Antidiuretic drugs used to reduce the fluid build-up in your body (such as hydrochlorothiazide, furosemide and spironolactone)
- Sildenafil, a drug used to treat erectile dysfunction
- Drugs used to treat HIV/AIDS
- Drugs used to treat heart rhythm disorders (such as amiodarone, disopyramide, flecainide digoxin)
- Fingolimod, a medicine used to treat multiple sclerosis
- Dexamethasone, a steroid drug used to treat inflammation
- Rifampin used to treat tuberculosis

How to take APO-NADOLOL:

Take APO-NADOLOL:

- Exactly as prescribed
- Everyday
- Once a day, at about the same time each day
- With or without food

Usual Adult Dose:

High Blood Pressure:

Usual starting daily dose: 80 mg once a day.

Maximum daily dose: 320 mg once a day.

Chest Pain:

Usual starting daily dose: 80 mg once a day.

Maximum daily dose: 240 mg once a day.

Do **NOT** stop taking **APO-NADOLOL** or change your dose without consulting with your doctor. This can be dangerous.

Overdose:

If you think you have taken too much APO-NADOLOL , contact your healthcare professional, hospital emergency department or regional Poison Control Centre

immediately, even if there are no symptoms.

Missed Dose:

If you have forgotten to take your dose, carry on and take your next dose at the usual time. **Do NOT** double the dose.

What are the possible side effects from taking APO-NADOLOL?

These are not all the possible side effects you may feel when you are taking **APO-NADOLOL**. If you experience any side effects not listed here, contact your healthcare professional.

Side effects may include:

- Cough
- Diarrhea
- Dizziness
- Dry mouth
- Headache
- Joint and back pain
- Nausea
- Stuffy nose and colds
- Tiredness
- Trouble sleeping

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
COMMON			
• Bradycardia: decreased heart rate that causes you to be dizzy or faint		✓	
• Chest pain			✓
UNCOMMON			
• Allergic reactions: rash, swelling of the lips, face or neck, difficulty breathing or speaking			✓
• Heart attack: chest pain, squeezing or pressure, fast or irregular heartbeat, nausea, trouble breathing, sweating			✓
• Heart conduction disorders: feeling lightheaded, dizzy, or passing out			✓

<ul style="list-style-type: none"> • Hypotension (low blood pressure): dizziness or lightheadedness leading to fainting can occur when changing positions, for example from lying down to standing up 		✓	
<ul style="list-style-type: none"> • Irregular heart beat or heart palpitations (skipped beats) 		✓	
<ul style="list-style-type: none"> • Leg swelling from fluid retention 		✓	
<ul style="list-style-type: none"> • Memory problems 		✓	
<ul style="list-style-type: none"> • Shortness of breath 		✓	
<ul style="list-style-type: none"> • Skin reactions: rash 	✓		
<ul style="list-style-type: none"> • Vision problems 	✓		

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

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 [MedEffect \(www.healthcanada.gc.ca/medeffect\)](http://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 0K9
 Postage paid labels and the Consumer Side Effect Reporting Form are available at [MedEffect](http://www.healthcanada.gc.ca/medeffect).

NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store tightly closed, at room temperature. Keep out of reach and sight of children

If you want more information about APO-NADOLOL:

- Talk to your healthcare professional.
- This leaflet plus the full product monograph, prepared for health professionals, can be found by visiting the Health Canada website (www.healthcanada.gc.ca). Find the Patient Medication Information on 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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