

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PATIENT MEDICATION INFORMATION

^{Pr} **APO-ATENIDONE** **atenolol and chlorthalidone tablets**

Read this carefully before you start taking **APO-ATENIDONE** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about APO-ATENIDONE.

What is APO-ATENIDONE used for?

APO-ATENIDONE is used to treat high blood pressure (also known as hypertension) in adults.

How does APO-ATENIDONE work?

APO-ATENIDONE contains two active ingredients: atenolol and chlorthalidone. Each active ingredient reduces blood pressure in a different way.

Atenolol belongs to a group of drugs called “beta blockers”.

- It makes your heart beat more slowly and less forcefully.

Chlorthalidone is a diuretic.

- It increases the amount of urine produced by the kidneys.

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

What are the ingredients in APO-ATENIDONE?

Medicinal ingredients: atenolol and chlorthalidone

Non-medicinal ingredients: microcrystalline cellulose, crospovidone, magnesium stearate, colloidal silicon dioxide

APO-ATENIDONE comes in the following dosage forms:

APO-ATENIDONE100/25 tablets: 100 mg atenolol and 25 mg chlorthalidone

Do not use APO-ATENIDONE if you:

- are allergic to atenolol, chlorthalidone or sulfonamide-derived drugs or any of the ingredients in APO-ATENIDONE.
- have slow or irregular heartbeats or if you have been told that you have heart block.
- have severe heart damage and your heart is not able to pump enough blood to meet your body’s needs.
- 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 a problem with your heart’s electrical conduction (that causes you to have chest pain, difficulty breathing, nausea, fatigue and fainting).
- have low blood pressure.
- have serious problems with blood flow in your feet and legs (peripheral artery disease).
- have loss of sensation with agents that cause heart failure.
- have a condition called pheochromocytoma (a tumour of the adrenal gland).

- have a condition called metabolic acidosis (abnormal levels of acids in your blood).
- are unable to produce urine.
- are pregnant, are trying or planning on becoming pregnant or breastfeeding.
- are 18 years or younger.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take APO-ATENIDONE. Talk about any health conditions or problems you may have, including if you:

- have a history of heart problems.
- have a history of fainting.
- have asthma or other lung problems (like bronchitis or emphysema).
- have thyroid problems.
- have liver or kidney problems.
- have circulation problems.
- have lupus or gout.
- have diabetes and take medicine to control your blood sugar or have low blood sugar (hypoglycemia).
- have ever been told that you suffer from a particular type of chest pain (angina), called Prinzmetal's angina.
- have had allergic reactions or have allergies.
- have had a surgery on a nerve (sympathectomy).
- are dehydrated or suffer from excessive vomiting, diarrhea, or sweating.
- develop a skin rash while taking APO-ATENIDONE.

Other warnings you should know about:

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

Tell your doctor if you are going into the hospital for an operation. If you go into the hospital, let the medical staff know and in particular the anaesthetist (if you are having an operation) that you are taking APO-ATENIDONE.

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

You may notice that your pulse rate becomes slower while taking APO-ATENIDONE. This is normal but if you are concerned, please talk to your doctor about it.

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

The following may interact with APO-ATENIDONE:

- drugs used for lowering blood pressure or treating angina:
 - beta-blockers (such as clonidine)
 - calcium channel blockers (such as verapamil, diltiazem or nifedipine)
 - catecholamine-depleting drugs (such as reserpine or guanethidine)

- vasodilators
- drugs used to treat irregular heartbeats (such as disopyramid or amiodarone)
- drugs used to treat heart failure (such as digoxin)
- non-steroidal anti-inflammatory agents (NSAIDs) (such as indomethacine or ibuprofen)
- anesthetic drugs used during surgery
- alcohol, sleeping pills (barbiturates) or strong pain medications (narcotics)
- norepinephrine, a heart stimulant
- lithium, a drug used to treat certain psychiatric disorders
- tubocurarine, a drug used to relax the muscles during surgery
- fingolimod, a drug used to treat multiple sclerosis

How to take APO-ATENIDONE:

Take APO-ATENIDONE:

- exactly as prescribed by your doctor.
- by swallowing the tablet whole with water.
- once a day, at the same time each day.

Your doctor will decide how much APO-ATENIDONE you should take each day depending on your condition.

If you have the impression that the effect of APO-ATENIDONE is too strong or too weak, talk to your doctor or pharmacist as soon as possible.

Do not stop taking APO-ATENIDONE or change your dose without consulting your doctor. This can be dangerous.

Usual Adult Dose: One tablet per day.

Overdose:

If you think you have taken too much APO-ATENIDONE, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

If you miss a dose, take the dose as soon as you remember. Do not take a double dose to make up for the missed dose.

What are possible side effects from using APO-ATENIDONE?

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

Side effects may include:

- cough
- cold fingers and toes
- diarrhea
- dizziness
- dry mouth

- headache
- joint and back pain
- nausea
- tiredness
- trouble sleeping
- vertigo

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			✓
Low levels of sodium or potassium in the blood: weakness, vomiting, and cramps		✓	
UNCOMMON			
Allergic reactions: rash, swelling of the lips, face or neck, difficulty breathing or speaking			✓
RARE			
Heart conduction disorders: feeling lightheaded, dizzy or passing out			✓
Hypotension (low blood pressure): dizziness or lightheadedness leading to fainting can occur when changing positions, for example from lying down to standing up		✓	
Irregular heart beat or heart palpitations (skipped beats)		✓	
Liver Disorder: yellowing of the skin or eyes, dark urine, abdominal pain, nausea. Vomiting, loss of appetite		✓	
Leg swelling from fluid retention		✓	
Memory problems		✓	
Inflammation of the Pancreas: abdominal pain that lasts and gets worse when you lie down, nausea, vomiting		✓	
Shortness of breath		✓	
Skin reactions: rash	✓		
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.

HOW TO STORE IT

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

Protect from light and moisture.

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

Keep 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.

If you want more information about APO-ATENIDONE:

- 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.html>). 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.

Last revised: February 12, 2019