

PART III: CONSUMER INFORMATION

Pr ACEBUTOLOL – 100
 Pr ACEBUTOLOL – 200
 Pr ACEBUTOLOL – 400
 (Acebutolol Hydrochloride)

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

ABOUT THIS MEDICATION**What the medication is used for:**

ACEBUTOLOL lowers high blood pressure (hypertension). ACEBUTOLOL can be used alone or with other medicines to treat this condition.

ACEBUTOLOL is also used to treat chest pains (angina) due to ischemic heart disease (disease caused by plaque building up along the inner walls of the arteries of the heart, which narrows the arteries and reduces blood flow to the heart).

What it does:

ACEBUTOLOL belongs to a class of drugs called "beta-blockers". These drugs block the action of certain chemicals on the heart that increase blood pressure and increase heart rate.

This medicine does not cure your disease. It helps to control it. Therefore, it is important to continue taking ACEBUTOLOL regularly even if you feel fine.

When it should not be used:**Do not take ACEBUTOLOL if you:**

- have any other medical problems, especially if you have heart rhythm disorders, heart failure,
- low blood pressure (hypotension), or other heart or circulation problems;
- have a tumour of the adrenal gland;
- are allergic or hypersensitive to acebutolol hydrochloride or other beta blocking drugs ("beta blockers"), or to any of the other nonmedicinal ingredients in ACEBUTOLOL

What the medicinal ingredient is:

acebutolol hydrochloride.

What the nonmedicinal ingredients are:

carnauba wax, colloidal silicon dioxide, dextrates, hydroxypropyl methylcellulose, magnesium stearate, polyethylene glycol and titanium dioxide.

What dosage forms it comes in:

Tablets, 100, 200, and 400 mg.

WARNINGS AND PRECAUTIONS

BEFORE you use ACEBUTOLOL, talk to your doctor, nurse or pharmacist if you:

- have psoriasis;
- have hyperthyroidism
- have any liver or kidney problems;
- have experienced heart failure in the past or have any other heart problems;
- have asthma, bronchitis, emphysema or chronic obstructive pulmonary disease (COPD);
- are currently taking any other prescription or over-the-counter medications;
- you have any known allergies;
- have diabetes or other problems with blood sugar levels;
- **are pregnant or thinking of becoming pregnant.** Taking ACEBUTOLOL during pregnancy may cause injury to you or your baby;
- **are breastfeeding.** ACEBUTOLOL passes from the mother into breast milk. You should not breast-feed while taking ACEBUTOLOL;
- are less than 18 years old.

If you have to undergo any dental or other surgery, inform the dentist or the doctor that you are taking ACEBUTOLOL.

Driving and using machines: Before you perform tasks which may require special attention, wait until you know how you respond to ACEBUTOLOL. Dizziness, and/or fatigue can especially occur after the first dose and when the dose is increased.

INTERACTIONS WITH THIS MEDICATION

As with most medicines, interactions with other drugs are possible. Tell your doctor, nurse, or pharmacist about all the medicines you take, including prescription and over-the counter medicines.

The following medicines may interact with ACEBUTOLOL:

- medicines used to treat high blood pressure, including clonidine and calcium channel blockers (*e.g.* oral verapamil, diltiazem). Your doctor should carefully monitor you if you are taking these in combination with ACEBUTOLOL. You may also have increased risk of depression if diltiazem is used with ACEBUTOLOL;
- Reserpine, a drug used to treat high blood pressure and severe agitation;
- medicines used to treat angina (chest pain), hypertension (high blood pressure) and abnormal heart rhythms such as beta-blockers (*e.g.*, atenolol, betaxolol, bisoprolol);
- medicines found in some cold remedies and nose drops (*e.g.* noradrenaline, isoprenaline, ephedrine, phenylephrine,

- phenylpropanolamine, xanthine derivative);
- medicines used to treat irregular heart beat (e.g., disopyramide, amiodarone);
- Digoxin (a heart medication);
- Fingolimod, a medicine used to treat multiple sclerosis;
- medicines used to treat asthma, bronchitis, emphysema, or lung disease (e.g. bronchodilators such as albuterol, epinephrine, salmeterol, terbutaline);
- Nonsteroidal anti-inflammatory drugs (NSAIDs), used to reduce pain and swelling (e.g. ibuprofen, naproxen, celecoxib);
- medicines used to treat depression, seizures, schizophrenia, or psychotic disorders (e.g., tricyclic antidepressants, barbiturates, phenothiazines, monoamine oxidase inhibitors);
- medicines used for anesthesia (e.g., ether, cyclopropane, trichloroethylene).

PROPER USE OF THIS MEDICATION

Your doctor will determine your dose based on your individual medical needs and will tell you when and how to take ACEBUTOLOL. Take ACEBUTOLOL exactly as prescribed. It is recommended to take your dose at about the same time every day. ACEBUTOLOL can be taken with or without food.

Usual adult dose:

To treat high blood pressure:

The usual starting dose is 100 mg twice a day. In some cases, your doctor may prescribe a higher dose or prescribe ACEBUTOLOL in combination with other drugs to treat your high blood pressure.

To treat chest pains due to heart disease:

The usual starting dose is 200 mg twice a day. In some cases, your doctor may prescribe a higher dose if needed, up to a maximum recommended dose of 300 mg twice per day.

For elderly patients and patients with kidney/liver problems:

Smaller doses are generally used in older patients, and those with kidney problems.

Do not stop taking ACEBUTOLOL or change your dose without first talking to your doctor. Serious side effects, such as chest pain or heart attack can occur if you abruptly stop taking this medication.

Overdose:

If you think you have taken too much ACEBUTOLOL, contact your doctor, nurse pharmacist, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

If you miss a dose, skip the missed dose and carry on with the next one at the usual time. Do not double the dose.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Side effects may include:

- tiredness,
- nausea
- dizziness
- skin rashes

You should report any side effects to your doctor.

ACEBUTOLOL can cause abnormal blood test results. Your doctor will decide when to perform blood tests and will interpret the results.

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 call your doctor or pharmacist
		Only if severe	In all cases	
Common	Low blood pressure: dizziness, fainting, lightheadedness May occur when you go from lying or sitting to standing up.	√		
	Skin rashes.		√	
	Nausea.	√		
Uncommon	Dry eyes		√	
	Narrowing of the airways (bronchospasm), or other lung effects.		√	
	Lupus-like syndrome: joint pain, muscle pain, chest pain when you cough or breath, breathing difficulties (shortness of breath or labored breathing)		√	
	Congestive heart failure: irregular heartbeat, low heart rate, or other changes in		√	

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

	heart symptoms.			
	Lung inflammations/ Pneumonia: cough, shortness of breath, chest pain, fever		√	
	Increased sensitivity or reactions to allergens.		√	
Unknown frequency	Liver disorders: yellowing of the skin or eyes, dark urine, abdominal pain, nausea, vomiting, loss of appetite		√	

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

HOW TO STORE IT

Keep ACEBUTOLOL and all medicines out of reach and sight of children.

Store between 15°C to 30°C. Protect from light.

Take ACEBUTOLOL that is out of date or no longer needed to your pharmacy or to your municipal waste disposal depot.

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 ACEBUTOLOL:

- 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>); or by contacting Pro Doc Ltée at 1-800-361-8559, www.prodoc.qc.ca or info@prodoc.qc.ca.

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