

PART III: CONSUMER INFORMATION

Pr OLMESARTAN

Olmesartan medoxomil tablets
5 mg, 20 mg, and 40 mg

Read this carefully before you start taking OLMESARTAN and each time you get a refill. This leaflet is a summary and will not tell you everything about Olmesartan. Talk to your doctor, nurse, or pharmacist about your medical condition and treatment and ask if there is any new information about Olmesartan.

ABOUT THIS MEDICATION

What the medication is used for:

OLMESARTAN is used to lower blood pressure in adults and children above 6 years old.

High blood pressure increases the workload of the heart and arteries. If this condition continues for a long time, damage to the blood vessels of the brain, heart, and kidneys can occur, and may eventually result in a stroke, heart or kidney failure. High blood pressure also increases the risk of heart attacks. Reducing your blood pressure decreases your risk of developing these illnesses.

What it does:

OLMESARTAN contains a drug olmesartan medoxomil which acts to inhibit the naturally occurring hormone, angiotensin II in the human body that causes the blood vessels to constrict. As an angiotensin receptor blocker (ARB), OLMESARTAN lowers blood pressure by relaxing the blood vessels and as a result blood pressure is lowered. You can recognize an ARB because its medicinal ingredient ends in “SARTAN”.

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

When it should not be used:

Do not take OLMESARTAN if you:

- Are allergic to olmesartan medoxomil or to any non-medicinal ingredient in the formulation.
- Have experienced an allergic reaction (angioedema) with swelling of the hands, feet, or ankles, face, lips, tongue, throat, or sudden difficulty breathing or swallowing, to any ARB. Be sure to tell your doctor, nurse, or pharmacist that this has happened to you.
- Are pregnant or intend to become pregnant. If this is the case, talk to your doctor as soon as possible. Taking OLMESARTAN during pregnancy can cause injury and even death to your baby.

- Are breastfeeding. It is possible that OLMESARTAN passes into breast milk.
- Are already taking a blood pressure-lowering medicine that contains aliskiren (such as Rasilez®) and you have diabetes or kidney disease.

OLMESARTAN is not recommended for use in children below the age of 6 years.

What the medicinal ingredient is:

Olmesartan medoxomil

What the nonmedicinal ingredients are:

Colloidal anhydrous silica, hydroxypropylcellulose, hypromellose, lactose monohydrate, low-substituted hydroxypropylcellulose, macrogols 400, magnesium stearate, microcrystalline cellulose, stearic acid, talc and titanium dioxide.

What dosage forms it comes in:

Film-coated Tablets: 5 mg, 20 mg and 40 mg.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

OLMESARTAN should not be used during pregnancy. If you discover that you are pregnant while taking Olmesartan, stop the medication and **please contact your doctor, nurse or pharmacist as soon as possible.**

BEFORE you use OLMESARTAN talk to your doctor or pharmacist if you:

- Have experienced an allergic reaction to any drug used to lower blood pressure.
- Have narrowing of a heart valve, heart or blood vessel disease.
- Have diabetes, liver or kidney disease.
- Are on dialysis.
- Are dehydrated or suffer from excessive vomiting, diarrhea, or sweating.
- Are on a low-salt diet.
- Are taking a salt substitute that contains potassium, potassium supplements, or a potassium-sparing diuretic (a specific kind of “water pill” that makes your body keep potassium).
- Are taking a medicine that contains aliskiren, such as Rasilez®, used to lower high blood pressure. The combination with OLMESARTAN is not recommended.
- Are taking an angiotensin converting enzyme inhibitor (ACEI). You can recognize ACEIs because their medicinal ingredient ends in “-PRIL”.

- Are less than 18 years old.

OLMESARTAN can cause severe chronic diarrhea with substantial weight loss (sprue-like enteropathy). It can take months to years for symptoms to develop.

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

INTERACTIONS WITH THIS MEDICATION

As with most medications, interactions with other drugs are possible. Tell your doctor, nurse, or pharmacist about all the medicines you take, including drugs prescribed by other doctors, vitamins, minerals, natural supplements, or alternative medicines.

The following may interact with Olmesartan:

- Agents increasing serum potassium, such as a salt substitute that contains potassium, potassium supplements, or a potassium-sparing diuretic (a specific kind of “water pill”).
- Blood pressure lowering drugs, including diuretics (“water pills”), aliskiren-containing products (e.g. Rasilez®), or angiotensin converting enzyme inhibitors (ACEIs).
- Lithium used to treat bipolar disease.
- Nonsteroidal anti-inflammatory drugs (NSAIDs), used to reduce pain and swelling. Examples include ibuprofen, naproxen, and celecoxib (COX-2 Inhibitor).

PROPER USE OF THIS MEDICATION

Usual dose:

For adult patients: 20 mg tablet once daily. It can be increased to 40 mg by your doctor if your blood pressure is not well controlled.

For pediatric patients age 6 to 16 of age:

Children weight between 20 Kg to less than 35 Kg: 10 mg once daily. If the blood pressure is not well controlled, your doctor can double the dosage to 20 mg once daily.

Children weight 35 Kg or more: 20 mg once daily.

If the blood pressure is not well controlled, your doctor can double the dosage to 40 mg once daily.

OLMESARTAN may be taken with or without food.

Overdose:

If you think you have taken too much Olmesartan, contact your doctor, nurse, pharmacist, 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 during the day, carry on with the next one at the usual time. Do not double dose.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Any medicine may have unintended or undesirable effects, so-called side effects.

Side effects may include:

- dizziness
- drowsiness, insomnia
- rash
- diarrhea, vomiting
- headache
- bronchitis
- back or leg pain, muscle pain and cramps
- upper respiratory tract infection

If any of these affects you severely, tell your doctor, nurse or pharmacist.

OLMESARTAN 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 to your healthcare professional		Stop taking drug and get immediate medical help
		Only if severe	In all cases	
Common	Low Blood Pressure: dizziness, fainting, lightheadedness.	✓		
	Increased levels of potassium in the blood: Irregular heartbeats, muscle		✓	

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN 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	
weakness and generally feeling unwell.			
Uncommon			
Allergic Reaction: rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing.			✓
Rhabdomyolysis: muscle pain that you cannot explain, muscle tenderness or weakness, dark brown urine.		✓	
Kidney Disorder: change in frequency of urination, nausea, vomiting, swelling of extremities, fatigue.		✓	
Liver Disorder: yellowing of the skin or eyes, dark urine, abdominal pain, nausea, vomiting, loss of appetite.		✓	
Decreased White Blood Cells: infections, fatigue, fever, aches, pains, and flu-like symptoms.		✓	
Decreased Platelets: bruising, bleeding, fatigue and weakness.		✓	
Unknown			
Sprue-like enteropathy: severe chronic diarrhea with substantial weight loss.		✓	

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

HOW TO STORE IT

The tablets should be stored at 15°C - 30°C.

Keep out of sight and reach of children and pets.

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](#);

- 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](#).

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

This document, plus the full product monograph prepared for health professionals, can be obtained by contacting Pro Doc Ltée at 1-800-361-8559, www.prodoc.qc.ca or info@prodoc.qc.ca

This leaflet was prepared by
Pro Doc Ltée
Laval, Québec
H7L 3W9

Revised on May 16, 2019

Rasilez® is a registered trademark of Novartis AG.