

PART III: CONSUMER INFORMATION

 OLMETEC®
(Olmesartan Medoxomil tablets)

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

ABOUT THIS MEDICATION

What the medication is used for:

OLMETEC® 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:

OLMETEC® 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), OLMETEC® 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 OLMETEC® regularly even if you feel fine.

When it should not be used:

Do not take OLMETEC® 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 OLMETEC® during pregnancy can cause injury and even death to your baby.
- Are breastfeeding. It is possible that OLMETEC® 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.

OLMETEC® 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:

Hydroxypropylcellulose, hydroxypropylmethylcellulose, lactose, low-substituted hydroxypropylcellulose, magnesium stearate, microcrystalline cellulose, talc, titanium dioxide, and yellow iron oxide (5 mg only*).

What dosage forms it comes in:

Film-Coated Tablets: 5 mg* (yellow, round shaped), 20 mg (white, round shaped), 40 mg (white, oval shaped).

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

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

BEFORE you use OLMETEC® 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 OLMETEC® 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.

OLMETEC® 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 OLMETEC®. Dizziness, lightheadedness, or fainting can especially occur after the first dose and when the dose is increased.

* 5 mg tablet not marketed

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 drugs prescribed by other doctors, vitamins, minerals, natural supplements, or alternative medicines.

The following may interact with OLMETEC®:

- 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.

OLMETEC® may be taken with or without food.

Overdose:

If you think you have taken too much OLMETEC® 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.

OLMETEC® 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.	√		
	Increased levels of potassium in the blood: irregular heartbeats, muscle 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 OLMETEC[®], contact your doctor or pharmacist.

HOW TO STORE IT

The tablets should be stored at 15–30 °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 1908C
 Ottawa, Ontario 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 found at: <http://www.merck.ca> or may be obtained by contacting the sponsor, Merck Canada Inc. at: 1-800-567-2594

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