

PART III: CONSUMER INFORMATION

Pr **OLMETEC**[®]

(Olmesartan Medoxomil)

This leaflet is part III of a three-part “Product Monograph” published when OLMETEC was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about OLMETEC. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

OLMETEC is used to lower blood pressure.

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. OLMETEC lowers blood pressure by specifically blocking the action of angiotensin II, and thus relaxing the blood vessels and as a result blood pressure is lowered.

When it should not be used:

You should not take OLMETEC if you:

- are pregnant or plan to become pregnant. If this is the case, talk to your doctor as soon as possible.
- are breastfeeding.
- are allergic to olmesartan medoxomil or to any other component of this product.

OLMETEC is not recommended for use in children and adolescents (below the age of 18 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 physician.

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

- You perform tasks which may require special attention (for example driving a vehicle or operating dangerous machinery). You should not perform these tasks until you know how you respond to your medication.
- You are taking other medicines to control your blood pressure.
- You are taking any medication including non-prescription or herbal products.
- You have recently suffered from excess vomiting or diarrhea.
- You have liver or kidney disease.
- You are pregnant or breastfeeding.
- You are allergic to this drug or its ingredients or components of the container.

Allergic reactions can occur in patients treated with OLMETEC.

If OLMETEC is taken with medicines to reduce pain and swelling (called Non-steroidal anti-inflammatory drugs (NSAIDs) or with COX-2 inhibitors), you may experience:

- Decreased kidney function or sudden kidney failure. If you notice a decrease in the amount of urine you produce, generalized swelling, weakness, shortness of breath, or irregular heartbeats, loss of appetite, lethargy, and fatigue, contact your doctor or go to the emergency department of the hospital right away.
- A decreased ability of OLMETEC to lower your blood pressure. This means that OLMETEC may not be able to lower your blood pressure as it is expected to do. If this happens, speak with your doctor or pharmacist.

Taking OLMETEC during pregnancy can cause injury and even death to your baby. This medicine should not be used during pregnancy. If you are planning to become pregnant while taking OLMETEC, contact immediately your doctor.

It is possible that OLMETEC passes into breast milk. You should discuss with your doctor about taking OLMETEC while breastfeeding.

INTERACTIONS WITH THIS MEDICATION

As with most medications, interaction with other drugs is possible. Therefore, do not take any other medication, including non-prescription and prescription drugs, unless you have discussed it with your doctor or your pharmacist.

Drugs that may interact with OLMETEC include:

- Medicines used to lower blood pressure, including diuretics (water pills)
- Potassium-sparing diuretics (potassium supplements or salt substitutes containing potassium)
- Lithium salts
- Medicines used to reduce pain and swelling called Nonsteroidal Anti-inflammatory Drugs (NSAIDs) and COX-2 Inhibitors

PROPER USE OF THIS MEDICATION

Usual dose:

The initial recommended dose is one 20 mg tablet once a day. If your blood pressure is not well controlled, your doctor may increase the dose to 40 mg, and/or decide to add another medicine (e.g. a thiazide diuretic).

OLMETEC may be taken with or without food.

Overdose:

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

Try to take OLMETEC daily as prescribed. However, if you miss a dose, do not take an extra dose. Just resume your usual schedule.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Any medicine may have unintended or undesirable effects, so-called side effects. Although most patients do not experience side effects when taking OLMETEC, some may experience dizziness, headache, bronchitis, back pain, diarrhea, or upper respiratory tract infection.

Tell your doctor or pharmacist about these or any other unusual symptoms.

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 seek immediate emergency medical attention
		Only if severe	In all cases	
Rare	Sudden Kidney Failure (sudden decrease or absence of urine, generalized swelling, weakness, shortness of breath, or irregular heartbeats, loss of appetite, lethargy and fatigue)			√
Very rare	Allergic Reactions (rash, swelling of the lips, face or neck, difficulty breathing or speaking)			√
	Hypotension (dizziness or light-headedness including fainting may occur due to low blood pressure)			√
	Dark/brown urine		√	
	Muscle pain		√	
	Bronchitis (shortness of breath, weakness, high fever, coughing and fatigue)		√	

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

Store at 15-30°C.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 0701D
Ottawa, Ontario
K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

or at Merck Canada Inc. by one of the following 2 ways:

- Call toll-free at 1-800-567-2594
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-496-9092, or
 - Mail to: Merck Canada Inc.
Pharmacovigilance
P.O. Box 1005
Pointe-Claire–Dorval, QC
H9R 4P8

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program or Merck do not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals may be obtained by contacting the sponsor, Merck Canada Inc. at: 1-800-567-2594.

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