

IMPORTANT: PLEASE READ

PART III: CONSUMER INFORMATION

Pr OLMETEC PLUS®

(Olmesartan medoxomil and hydrochlorothiazide)

This leaflet is part III of a three-part "Product Monograph" published when OLMETEC PLUS 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 PLUS. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

OLMETEC PLUS is used to lower blood pressure where treatment with just one drug is not effective.

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 PLUS contains a combination of two drugs. The drug olmesartan medoxomil acts to inhibit the naturally occurring hormone, angiotensin II in the human body that causes the blood vessels to constrict. The drug hydrochlorothiazide acts by inducing diuresis (urination) which leads to decreased amount of body water which is beneficial in patients with high blood pressure.

When it should not be used:

Do not take OLMETEC PLUS if you:

- are allergic to olmesartan medoxomil, hydrochlorothiazide, or to any other ingredient;
- are allergic to sulphonamide-derived drugs;
- are pregnant or plan to become pregnant. If this is the case, talk to your doctor as soon as possible;
- are breastfeeding.

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

If you are not sure whether you should start taking OLMETEC PLUS, contact your physician or pharmacist.

What the medicinal ingredients are:

Olmesartan medoxomil and hydrochlorothiazide

What the important nonmedicinal ingredients are:

Hydroxypropylcellulose, hypromellose, lactose, low-substituted hydroxypropylcellulose, magnesium stearate, microcrystalline cellulose, red iron oxide, talc, titanium dioxide and yellow iron oxide.

What dosage forms it comes in:

Film-Coated Tablets: 20 mg/12.5 mg (reddish-yellow, circular shaped), 40 mg/12.5 mg (reddish-yellow, oval shaped), or 40 mg/25 mg (pink, oval shaped).

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

OLMETEC PLUS should not be used during pregnancy. If you discover that you are pregnant while taking OLMETEC PLUS, stop the medication and please contact your physician.

BEFORE you use OLMETEC PLUS 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, gout, diabetes, lupus erythematosus, or if you are being treated with other diuretics (water tablets).
- You have difficulty urinating.
- You are allergic to penicillin or sulfonamide-derived drugs.
- You have to undergo any kind of surgery and general anesthesia.
- 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 PLUS.

One of the medicines in OLMETEC PLUS can cause eye problems that may lead to vision loss. Symptoms of eye problems can happen within hours to weeks of starting OLMETEC PLUS. Tell your doctor right away if you have:

- decrease in vision
- eye pain

If OLMETEC PLUS 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 PLUS to lower your blood pressure. This means that OLMETEC PLUS 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 PLUS 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 PLUS, contact immediately your doctor.

It is possible that OLMETEC PLUS passes into breast milk. You should discuss with your doctor about taking OLMETEC PLUS 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 PLUS include:

- Medicines used to lower blood pressure, including diuretics (water pills)
- Potassium-sparing diuretics (water pills)
- Potassium supplements or salt substitutes containing potassium
- Lithium salts
- Antidiabetic agents (insulin)
- Resins which reduce high cholesterol level

- Corticosteroids
- Medicines used to reduce pain and swelling called Non-steroidal anti-inflammatory drugs (NSAIDs) and COX-2 Inhibitors
- Sympathomimetics
- Anesthetics
- Certain pain and arthritis medicines
- Curare derivatives (muscle relaxants)
- Allopurinol (anti-gout treatment)
- Amantadine
- Cytotoxic drugs (cancer therapy)
- Anticholinergic agents
- Cyclosporine
- Digoxin (a heart medicine)

Avoid alcoholic beverages until you have discussed their use with your physician. Alcohol consumption may alter your blood pressure.

PROPER USE OF THIS MEDICATION

Dosage must be individualized. OLMETEC PLUS is not for initial therapy.

Usual dose:

The usual recommended dose is in the range of 20/12.5 to 40/25 mg once a day. Take OLMETEC PLUS every day exactly as your physician has instructed in order to maintain your blood pressure.

OLMETEC PLUS 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 PLUS 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 PLUS, some patients may experience dizziness, headache, nausea, fatigue, and 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	
Uncommon	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)			√
	Bronchitis (shortness of breath, weakness, high fever, coughing and fatigue)		√	
	Eye problems that may lead to vision loss (decrease in vision, eye pain)		√	
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)			√

This is not a complete list of side effects. For any unexpected effects while taking OLMETEC PLUS, 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.

This leaflet was prepared by Merck Canada Inc.

Last revised: August 16, 2011

® Registered trademark of Daiichi Sankyo Company, Limited. Used under license.

©2011, Merck Canada Inc., a subsidiary of **Merck & Co., Inc.** All rights reserved.

