

PART III: CONSUMER INFORMATION**OLMETEC PLUS®**

(Olmesartan medoxomil and hydrochlorothiazide)

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

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

OLMETEC PLUS® lowers high blood pressure.

What it does:

OLMETEC PLUS® contains a combination of two drugs, olmesartan medoxomil and hydrochlorothiazide:

- Olmesartan medoxomil is an angiotensin receptor blocker (ARB). You can recognize an ARB because its medicinal ingredient ends in “-SARTAN”. It lowers blood pressure.
- Hydrochlorothiazide is a diuretic or “water pill” that increases urination. This lowers blood pressure.

This medicine does not cure high blood pressure. It helps to control it. Therefore, it is important to continue taking OLMETEC PLUS® regularly even if you feel fine.

When it should not be used:

Do not take OLMETEC PLUS® if you:

- Are allergic to olmesartan medoxomil, hydrochlorothiazide or to any non-medicinal ingredient in the formulation or components of the container.
- Are allergic to any sulphonamide-derived drugs (sulfa drugs): most of them have a medicinal ingredient that ends in “-MIDE”.
- 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 (any drug in the same class as OLMETEC). Be sure to tell your doctor, nurse, or pharmacist that this has happened to you.
- Have difficulty urinating or produce no urine.
- Are pregnant or intend to become pregnant. Taking OLMETEC PLUS® during pregnancy can cause injury and even death to your baby.
- Are breastfeeding. OLMETEC PLUS® 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.
- Have one of the following rare hereditary diseases
 - Galactose intolerance
 - Lapp lactase deficiency
 - Glucose-galactose malabsorption

Because lactose is a non-medicinal ingredient in OLMETEC PLUS®.

What the medicinal ingredients are:

Olmesartan medoxomil and hydrochlorothiazide

What the non-medicinal 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:

Tablets: 20 mg/12.5 mg, 40 mg/12.5 mg and 40 mg/25 mg.

WARNINGS AND PRECAUTIONS**Serious Warnings and Precautions - Pregnancy**

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

BEFORE you use OLMETEC PLUS® talk to your doctor, nurse or pharmacist if you:

- Are allergic to any drug used to lower blood pressure, including angiotensin converting enzyme (ACE) inhibitors, or penicillin.
- Have narrowing of an artery or a heart valve.
- Have had a heart attack or stroke.
- Have heart failure.
- Have diabetes, liver or kidney disease.
- Are taking a medicine that contains aliskirin, such as Rasilez, used to lower high blood pressure. The combination with OLMETEC PLUS® is not recommended.
- Are taking an angiotensin converting enzyme inhibitor (ACEI). You can recognize ACEIs because their medicinal ingredient ends in “-PRIL”.
- Have lupus or gout.
- Are on dialysis.
- Are dehydrated or suffer from excessive vomiting, diarrhea, or sweating.
- Are taking a salt substitute that contains potassium, potassium supplements, or a potassium-sparing diuretic (a specific kind of “water pill”).
- Are on a low-salt diet.
- Are less than 18 years old.
- Are taking any medication including non-prescription or herbal products.
- You have to undergo any kind of surgery and general anesthesia.

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

Hydrochlorothiazide in OLMETEC PLUS® can cause Sudden Eye Disorders:

- **Myopia:** sudden nearsightedness or blurred vision.
- **Glaucoma:** an increased pressure in your eyes, eye pain. Untreated, it may lead to permanent vision loss. These eye disorders are related and can develop within hours to weeks of starting OLMETEC PLUS®.

You may become sensitive to the sun while taking OLMETEC PLUS®. Exposure to sunlight should be minimized until you know how you respond.

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

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

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.

INTERACTIONS WITH THIS MEDICATION

As with most medications, interaction 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 PLUS®:

- Adrenocorticotrophic hormone (ACTH) used to treat West Syndrome
- Alcohol, barbiturates (sleeping pills), or narcotics (strong pain medications). They may cause low blood pressure and dizziness when you go from lying or sitting to standing up.
- Amphotericin B, an antifungal drug.
- Anticancer drugs, including cyclophosphamide and methotrexate.
- Antidepressants, in particular selective serotonin reuptake inhibitors (SSRIs), including citalopram, escitalopram, and sertraline.
- Antidiabetic drugs, including insulin and oral medicines.
- Bile acid resins used to lower cholesterol.
- Other blood pressure lowering drugs. When taken in combination with OLMETEC PLUS®, they may cause excessively low blood pressure.
- Calcium or vitamin D supplements.
- Corticosteroids used to treat joint pain and swelling.
- Digoxin, a heart medicine.
- Drugs that slow down or speed up bowel function, including atropine, metoclopramide and domperidone.
- Drugs used to treat epilepsy, including carbamazepine and topiramate.
- Gout medications, including allopurinol and probenecid.
- Lithium used to treat bipolar disease.

- Nonsteroidal anti-inflammatory drugs (NSAIDs), used for arthritis and to reduce pain and swelling. Examples include ibuprofen, naproxen, and celecoxib.
- Skeletal muscle relaxants used to relieve muscle spasms, including tubocurarine.
- Pressor amines such as norepinephrine.
- Sympathomimetics
- Anesthetics
- Amantadine
- Anticholinergic agents
- Cyclosporine
- Blood pressure-lowering drugs, including diuretics (“water pills”), aliskiren-containing products (e.g. Rasilez), or angiotensin converting enzyme inhibitors (ACEIs).

PROPER USE OF THIS MEDICATION

Take OLMETEC PLUS® exactly as prescribed. It is recommended to take your dose at about the same time everyday.

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

OLMETEC PLUS® may be taken with or without food. If OLMETEC PLUS® causes upset stomach, take it with food or milk.

Usual Adult dose:

One tablet daily.

Overdose:

If you think you have taken too much OLMETEC PLUS® 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

Side effects may include:

- upper respiratory tract infection, cough.
- back or leg pain, muscle cramps, spasms and pain, weakness, restlessness
- dizziness, pins and needles in your fingers, headache
- constipation, diarrhea, nausea, vomiting, decreased appetite, upset stomach, enlargement of the glands in your mouth
- bleeding under the skin, rash, red patches on the skin
- fatigue, drowsiness, insomnia
- reduced libido

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

OLMETEC PLUS® 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, nurse or pharmacist		Stop taking drug and seek immediate medical help
		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.	√		
	Decreased or increased levels of potassium in the blood: irregular heartbeats, muscle weakness and generally feeling unwell.		√	
	Chest Pain:	√		
	Edema: Swelling of the hands, ankles or feet.	√		
Uncommon	Allergic Reaction: rash, hives, swelling of the lips, face, tongue or throat difficulty swallowing or breathing.			√
	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.		√	
	Increased blood sugar: frequent urination, thirst, and hunger.	√		
	Electrolyte Imbalance: weakness, drowsiness, muscle pain or cramps, irregular heartbeat.		√	
	Bronchitis: shortness of breath, weakness, high fever, coughing and fatigue.		√	

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

Symptom/effect		Talk with your doctor, nurse or pharmacist		Stop taking drug and seek immediate medical help
		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).			√
	Rhabdomyolysis: muscle pain that you cannot explain, muscle tenderness or weakness, dark brown urine.		√	
	Decreased White Blood Cells: infections, fatigue, fever, aches, pains, and flu-like symptoms.		√	
	Decreased Platelets: bruising, bleeding, fatigue and weakness.		√	
Very Rare	Toxic Epidermal Necrolysis: severe skin peeling, especially in mouth and eyes.			√
Unknown	Eye disorders: - Myopia: sudden near sightedness or blurred vision - Glaucoma: increased pressure in your eyes, eye pain.			√
	Anemia: fatigue, loss of energy, weakness, shortness of breath.		√	
	Inflammation of the Pancreas: abdominal pain that lasts and gets worse when you lie down, nausea, vomiting.		√	
	Palpitations: Irregular heartbeats.	√		
	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 PLUS®, contact your doctor or pharmacist.

HOW TO STORE IT

Store at 15-30°C.

Keep out of reach and sight of children.

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 by contacting the sponsor, Merck Canada Inc. at:
1-800-567-2594.

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