

Patient Medication Information

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrOLMETEC PLUS®

olmesartan medoxomil and hydrochlorothiazide tablets

This Patient Medication Information is written for the person who will be taking OLMETEC PLUS. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This Patient Medication Information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about OLMETEC PLUS, talk to a healthcare professional.

Serious warnings and precautions box

Pregnancy:

- OLMETEC PLUS should not be used during pregnancy. Taking OLMETEC PLUS during pregnancy can cause harm and even death to your baby. If you discover that you are pregnant while taking OLMETEC PLUS, stop the medication as soon as possible and talk to your healthcare professional.

What OLMETEC PLUS is used for:

OLMETEC PLUS is used to lower blood pressure in adults.

How OLMETEC PLUS works:

OLMETEC PLUS contains a combination of two medicinal ingredients, olmesartan medoxomil and hydrochlorothiazide:

- Olmesartan medoxomil is an angiotensin receptor blocker (ARB). It acts to prevent the hormone in your body that causes the blood vessels to constrict. It lowers blood pressure by relaxing the blood vessels.
- Hydrochlorothiazide is a diuretic or “water pill”. This lowers blood pressure by increasing urination.

OLMETEC PLUS 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.

The ingredients in OLMETEC PLUS are:

Medicinal ingredients: olmesartan medoxomil and hydrochlorothiazide

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

OLMETEC PLUS comes in the following dosage forms:

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

Do not use OLMETEC PLUS if:

- you are allergic to olmesartan medoxomil, hydrochlorothiazide or to any of the non-medicinal ingredients in OLMETEC PLUS (see **The ingredients in OLMETEC PLUS are**).

- you are allergic to any sulphonamide-derived drugs. Most of them have a medicinal ingredient that ends in “-MIDE”.
- you have experienced an allergic reaction with swelling of the hands, feet, or ankles, face, lips, tongue, throat, or sudden difficulty breathing or swallowing to any ARB (Angiotensin Receptor Blocker). You can recognize an ARB because its medicinal ingredient ends in “-SARTAN”. Be sure to tell your healthcare professional that this has happened to you.
- you have problems passing urine-or produce no urine.
- you are pregnant or plan to become pregnant. Taking OLMETEC PLUS during pregnancy can cause harm and even death to your baby.
- you are breastfeeding. It is possible that OLMETEC PLUS passes into breast milk.
- you have diabetes or kidney disease and are already taking medicine that contains aliskiren (such as Rasilez), which is used to lower high blood pressure.
- you 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.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take OLMETEC PLUS. Talk about any health conditions or problems you may have, including if you:

- have a greater chance of developing skin cancer because you:
 - had skin cancer or have a family history of skin cancer
 - have light-coloured skin
 - sunburn easily
 - take medicine to suppress your immune system
- are allergic to any medicine used to lower blood pressure, including angiotensin converting enzyme (ACE) inhibitors.
- are allergic to the penicillin (antibiotic drug).
- have a narrow artery or a heart valve.
- had a heart attack or have heart or blood vessel disease.
- had a stroke or have a condition that affects the blood supply to the brain.
- have liver or kidney problems.
- have blocked bile ducts.
- 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 (ACE) inhibitors). You can recognize ACE inhibitors because their medicinal ingredient ends in “-PRIL”.
- have lupus or gout.
- have diabetes.
- 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.
- have asthma.
- are taking any medication including non-prescription or herbal products.
- have to undergo any kind of surgery and general anesthesia.
- have had breathing or lung problems (including inflammation or fluid in the lungs) in the past following the

use of medication containing hydrochlorothiazide. If you experience any severe shortness of breath or difficulty breathing after taking OLMETEC PLUS, stop the medication and seek medical attention immediately.

Other warnings you should know about:

Spruce-like enteropathy: OLMETEC PLUS cause severe chronic diarrhea with substantial weight loss (spruce-like enteropathy). It can take months to years for symptoms to develop. Talk to your healthcare professional if you experience diarrhea while taking OLMETEC PLUS.

Pregnancy: OLMETEC PLUS can cause harm to your unborn baby. Taking OLMETEC PLUS during pregnancy can:

- prevent the normal growth of your baby's kidneys and skull if you take it during the second and third trimester. Your healthcare professional may recommend an ultrasound.
- cause your baby's eyes and skin to turn yellow after birth.
- lower the level of platelets in your baby's blood. This can cause bleeding by affecting the ability of your baby's blood to clot.

Risk of skin cancer: OLMETEC PLUS contains the medicinal ingredient hydrochlorothiazide. Treatment with hydrochlorothiazide may increase the risk of developing non-melanoma skin cancer. The risk is higher if you have been taking OLMETEC PLUS for many years (more than 3) or at a high dose.

While taking OLMETEC PLUS:

- Make sure to regularly check your skin for any new lesions (such as a lump, bump, sore, or patch). Check areas that are most exposed to the sun, such as the face, ears, hands, shoulders, upper chest and back. Talk to your healthcare professional immediately if you develop new skin lesions.
- Limit your exposure to the sun and to indoor tanning.
- Always use sunscreen (SPF-30 or higher).
- Protect your skin when going outside by covering your skin with clothing and a hat.
- You may become sensitive to the sun. Talk to your healthcare professional immediately if you get more sensitive to the sun or UV light.

Eye problems: Hydrochlorothiazide in OLMETEC PLUS can cause sudden eye disorders:

- **Choroidal effusion:** an abnormal building of liquid in your eye that may result in vision changes.
- **Myopia:** sudden nearsightedness or blurred vision.
- **Glaucoma:** an increased pressure in your eyes, eye pain. If left untreated, it may lead to permanent vision loss.

If your vision changes, stop taking OLMETEC PLUS and seek immediate medical help. These eye disorders are related and can develop within hours to weeks of starting OLMETEC PLUS.

Driving and using machines: Before you perform tasks which may require special attention, wait until you know how you respond to OLMETEC PLUS. Dizziness, light-headedness, or fainting can occur when you take OLMETEC PLUS for the first time and when your dose is increased.

Use with alcohol: Avoid drinking alcohol until you have discussed this with your healthcare professional. Drinking alcohol may lower your blood pressure and may cause you to feel sudden dizziness when you stand up.

Use with pain medication: If you take OLMETEC PLUS with medicines that reduce pain and swelling (Non-

steroidal anti-inflammatory drugs (NSAIDs) or COX-2 inhibitors), you may experience:

- A decline in kidney function or sudden kidney failure. Talk to your healthcare professional and get immediate medical help 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
- A decrease in the 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, talk to your healthcare professional.

Blood tests and monitoring: OLMETEC PLUS can cause abnormal blood test results, including lower levels of sodium, chloride and potassium in your blood. Your healthcare professional will decide when to perform blood tests and will interpret the results.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with OLMETEC PLUS:

- Adrenocorticotrophic hormone (ACTH), used to treat West Syndrome.
- Agents that increase potassium in the blood, such as a salt substitute that contains potassium, potassium supplements, or a potassium-sparing diuretic (a specific kind of “water pill”).
- Alcohol, barbiturates (sleeping pills), or narcotics (strong pain medications).
- Amantadine, used to treat Parkinson’s disease.
- Amphotericin B, an antifungal drug.
- Anesthetics, used to prevent pain and sensation during surgery or medical procedures.
- Anticancer drugs, including cyclophosphamide and methotrexate.
- Anticholinergic agents, used to treat conditions such as chronic obstructive pulmonary disorder (COPD), overactive bladder and Parkinson’s disease.
- 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.
- Blood pressure-lowering drugs, including diuretics (“water pills”), aliskiren-containing products (e.g. Rasilez), or angiotensin converting enzyme inhibitors ACE inhibitors.
- Calcium or vitamin D supplements.
- Corticosteroids, used to treat joint pain and swelling.
- Cyclosporine, used to suppress the immune system.
- 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 (COX-2 Inhibitor).

- Skeletal muscle relaxants, used to relieve muscle spasms, including tubocurare.
- Pressor amines such as norepinephrine, used in medical setting to treat shock.
- Sympathomimetics, used to treat conditions such as cardiac arrest, severe allergic reactions and low blood pressure.

How to take OLMETEC PLUS:

- Take OLMETEC PLUS exactly as your healthcare professional tells you to. Do NOT take more of it than prescribed.
- It is recommended to take your dose at about the same time everyday.
- OLMETEC PLUS is not for initial treatment.
- OLMETEC PLUS may be taken with or without food.

Usual dose:

Take one tablet daily. More than one tablet daily is not recommended.

Overdose:

If you think you, or a person you are caring for, have taken too much OLMETEC PLUS, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

Missed Dose:

If you missed a dose of this medication, you do not need to make up the missed dose. Skip the missed dose and continue with your next scheduled dose. Do not take two doses at the same time.

Possible side effects from using OLMETEC PLUS:

These are not all the possible side effects you may have when taking OLMETEC PLUS. If you experience any side effects not listed here, tell your healthcare professional.

Side effects may include:

- Back pain
- Decreased appetite
- Dizziness, headache
- Fatigue
- Gastrointestinal problems:
 - Constipation
 - Diarrhea
 - Nausea
 - Upset stomach
 - Vomiting
- Joint pain
- Muscle cramps, spasms and pain
- Rash, red itchy patches on the skin
- Restlessness and weakness
- Upper respiratory tract infection:
 - Congested and runny nose

- Cough
- Sore throat

Serious side effects and what to do about them

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
Common			
Ear Disorder (vertigo): a sense of dizziness, spinning.		√	
Urinary Track Infections: difficulty and pain when passing urine, exaggerated sense of needing to urinate, blood in urine and cloudy urine.		√	
Non-melanoma Skin Cancer: lump or discoloured patch on the skin that stays after a few weeks and slowly changes. Cancerous lumps are red/pink and firm and sometimes turn into ulcers. Cancerous patches are usually flat and scaly.		√	
Hematuria (blood in urine): pink, red or very dark urine.		√	
High Blood Sugar: frequent urination, increased thirst, dry skin, headache, blurred vision and fatigue.	√		
Low Blood Pressure: dizziness, fainting, light-headedness (may occur when you go from lying or sitting to standing up).	√		
Chest Pain: painful pressure or tightness in your chest.	√		
Edema: unusual swelling of the arms, legs, ankles or feet.	√		
Allergic Reaction: rash, hives, swelling of the lips, face, tongue or throat-difficulty swallowing or breathing.			√
Uncommon			
Kidney Problems: change in frequency of urination, nausea, vomiting, swelling of extremities, fatigue.		√	
Liver Problems: yellowing of the skin or eyes, dark urine, abdominal		√	

pain, nausea, vomiting, loss of appetite.			
Rare			
Acute Kidney Failure: decrease or absence of urine, generalized swelling, weakness, shortness of breath, or irregular heartbeats, loss of appetite, lethargy and fatigue.			√
Increased Levels of Potassium in the Blood: irregular heartbeats, muscle weakness and generally feeling unwell.		√	
Rhabdomyolysis (breakdown of damaged muscles): muscle pain that you cannot explain, muscle tenderness or weakness, dark brown urine.		√	
Palpitation (fast-beating, fluttering or pounding heart): skipping beats, beating too fast, pounding, fluttering rapidly.	√		
Very rare			
Acute Respiratory Distress Syndrome (ARDS) (inflammation of lung tissue or excess fluid in the lungs): severe shortness of breath or difficulty breathing, fever, weakness, and confusion.			√
Unknown			
Anemia (decreased number of red blood cells): fatigue, loss of energy, weakness, shortness of breath.		√	
Spruce-like Enteropathy: severe chronic diarrhea with substantial weight loss.		√	
Eye Disorders: - Myopia: sudden near sightedness or blurred vision - Glaucoma: increased pressure in your eyes, eye pain, decrease in vision - Choroidal effusion (buildup of liquid in your eye): blind spots, eye pain, blurred vision			√

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting side effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (canada.ca/drug-device-reporting) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store at 15-30°C.

Keep out of reach and sight of children.

If you want more information about OLMETEC PLUS:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada Drug Product Database website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database>); the Organon Canada website www.organon.ca or by calling Organon Canada at 1-844-820-5468.

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