

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PATIENT MEDICATION INFORMATION

OLMETEC PLUS®

Olmesartan Medoxomil and Hydrochlorothiazide **Tablets**

Read this carefully before you start taking **OLMETEC PLUS® (Olmesartan Medoxomil and Hydrochlorothiazide)** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about OLMETEC PLUS®.

Serious Warnings and Precautions - 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 contact your doctor.

What is OLMETEC PLUS® used for?

OLMETEC PLUS® is used to lower blood pressure in adults.

How does OLMETEC PLUS® work?

OLMETEC PLUS® contains a combination of two drugs, 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.

What are the ingredients in OLMETEC PLUS®?

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 other ingredients of OLMETEC PLUS®.
- Are allergic to any sulphonamide-derived drugs. Most of them have a medicinal ingredient that ends in “-MIDE”.
- 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 doctor, nurse, or pharmacist that this has happened to you.

- Have problems passing urine–or produce no urine.
- Are pregnant or intend to become pregnant. Taking OLMETEC PLUS® during pregnancy can cause harm and even death to your baby.
- Are breastfeeding. It is possible that OLMETEC PLUS® passes into breast milk.
- Have diabetes or kidney disease and are already taking medicine that contains aliskiren (such as Rasilez), which is used to lower high blood pressure.
- Have one of the following rare hereditary diseases:
 - Galactose intolerance
 - Lapp lactase deficiency
 - Glucose-galactose malabsorption

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 drugs to suppress your immune system
- Are allergic to any drug 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 disease.
- 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.

Other warnings you should know about:

OLMETEC PLUS® can:

- cause severe chronic diarrhea with substantial weight loss (sprue-like enteropathy). It can take months to years for symptoms to develop.
- lower the levels of sodium, chloride and potassium in the blood.

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 the drug during the second and third trimester. Your doctor 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.

Risk of skin cancer:

OLMETEC PLUS® contains 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 doctor 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 doctor immediately if you get more sensitive to the sun or UV light.

Hydrochlorothiazide in OLMETEC PLUS® can cause Sudden Eye Disorders. These disorders can develop within hours to weeks of starting OLMETEC PLUS®:

- **Sudden Myopia (nearsightedness):** objects further away appear blurry.
- **Sudden Glaucoma:** blurred vision increased pressure in your eyes, and eye pain. It may lead to permanent vision loss if left untreated.

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 occur when you take the drug for after the first time and when your dosage is increased.

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

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. Contact your doctor and go to the emergency department immediately 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, speak with your doctor or pharmacist.

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

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.
- 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”).
- Alcohol, barbiturates (sleeping pills), or narcotics (strong pain medications).
- Amantadine.
- Amphotericin B, an antifungal drug.
- Anesthetics.
- Anticancer drugs, including cyclophosphamide and methotrexate.
- Anticholinergic agents.
- 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.
- 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 tubocurarine.
- Pressor amines such as norepinephrine.
- Sympathomimetics.

How to take OLMETEC PLUS®?

- Take OLMETEC PLUS® exactly as prescribed. 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 have taken too much OLMETEC PLUS®, contact your healthcare professional, 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.

What are possible side effects from using OLMETEC PLUS®

These are not all the possible side effects you may feel when taking OLMETEC PLUS®. If you experience any side effects not listed here, contact your doctor.

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

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 and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking 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, lightheadedness.	√		
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 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.		√	

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.	√		
UNKNOWN			
Anemia (decreased number of red blood cells): fatigue, loss of energy, weakness, shortness of breath.		√	
Sprue-like Enteropathy: severe chronic diarrhea with substantial weight loss.		√	

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

<p>Reporting Side Effects</p> <p>You can report any suspected side effects associated with the use of health products to Health Canada by:</p> <ul style="list-style-type: none"> • Visiting the Web page on Adverse Reaction Reporting https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html for information on how to report online, by mail or by fax; or • Calling toll-free at 1-866-234-2345. <p><i>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.</i></p>
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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 website <https://health-products.canada.ca/dpd-bdpp/index-eng.jsp> or the Organon Canada website www.organon.ca or by calling Organon Canada at 1-844-820-5468.

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