PART III: CONSUMER INFORMATION

[Pr]TEVETEN® PLUS
eprosartan mesylate/hydrochlorothiazide tablets

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

ABOUT THIS MEDICATION

What the medication is used for:

TEVETEN® PLUS is a medication that helps to control high blood pressure.

What it does:

TEVETEN® PLUS contains a combination of 2 drugs, eprosartan mesylate and hydrochlorothiazide:

- Eprosartan mesylate 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 TEVETEN® PLUS regularly even if you feel fine.

When it should not be used:

Do not take TEVETEN® PLUS if you:

- Are allergic to eprosartan mesylate, hydrochlorothiazide or to any non-medicinal ingredient in the formulation.
- Are allergic to any sulfonamide-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. Be sure to tell your doctor, nurse, or pharmacist that this has happened to you.
- Have difficulty urinating or produce no urine.
- Have kidney or liver problems
- Are pregnant or intend to become pregnant. Taking TEVETEN® PLUS during pregnancy can cause injury and even death to your baby.
- Are breastfeeding. TEVETEN® PLUS passes into breast milk.
- Have electrolyte imbalances which are difficult to treat (low potassium, sodium or high calcium blood levels).
- Have symptoms of gout or abnormally high levels of uric acid in the blood.
- Have one of the following rare hereditary diseases:
  - Galactose intolerance
  - Lapp lactase deficiency
  - Glucose-galactose malabsorption

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

- Have diabetes or kidney disease and are already taking a blood pressure-lowering medicine that contains aliskiren (such as Rasilez®), or an angiotensin converting enzyme (ACE) inhibitor. You can recognize ACE inhibitors because the name of their medicinal ingredient ends in "-pril".

What the medicinal ingredient are:

Eprosartan mesylate and hydrochlorothiazide

What the non-medicinal ingredients are:

Crospovidone, iron oxide black, iron oxide yellow, lactose monohydrate, macrogol 3350, magnesium stearate, microcrystalline cellulose, polyvinyl alcohol, pregelatinized starch, talc and titanium dioxide.

What dosage forms it comes in:

Film-coated tablets; eprosartan mesylate / hydrochlorothiazide: 600 mg/12.5 mg.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions – Pregnancy

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

BEFORE you use TEVETEN® 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 heart failure.
- Have diabetes, liver or kidney disease.
- 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, a potassium-sparing diuretic (a specific kind of "water pill"), or other medicines that may increase serum potassium.
- Are taking a medicine that contains aliskiren, such as Rasilez®, used to lower high blood pressure. The combination with TEVETEN® PLUS is not recommended.
- Are taking an angiotensin converting enzyme inhibitor (ACEI). You can recognize ACEIs because their medicinal ingredient ends in '-**PRIL**'.
- Are on a low-salt diet.
- Have excessive blood level of aldosterone.
- Are less than 18 years old.
- Have had skin cancer or have a family history of skin cancer.
- Have a greater chance of developing skin cancer because you have light-coloured skin, get sunburned easily, or are taking drugs to suppress your immune system.

Risk of skin cancer:
TEVETEN® 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 TEVETEN® PLUS for many years (more than 3) or at a high dose.

While taking TEVETEN® PLUS:
- Make sure to regularly check your skin for any new lesions. Check areas that are most exposed to the sun, such as the face, ears, hands, shoulders, upper chest and back.
- Limit your exposure to the sun and to indoor tanning. Always use sunscreen (SPF-30 or higher) and wear protective clothing when going outside.
- Talk to your doctor immediately if you get more sensitive to the sun or UV light or if you develop an unexpected skin lesion (such as a lump, bump, sore, or patch) during the treatment.

Hydrochlorothiazide in TEVETEN® 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.
- **Choroidal effusion:** an abnormal buildup of liquid in your eye that may result in vision changes.

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

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

Hydrochlorothiazide in TEVETEN® PLUS may lead to positive result in doping tests.

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

INTERACTIONS WITH THIS MEDICATION

As with most medicines, interactions 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 TEVETEN® PLUS:

- Agents increasing serum potassium, such as salt substitute that contains potassium, potassium supplements, a potassium-sparing diuretic (a specific kind of "water pill").
- Blood pressure-lowering drugs, including diuretics ("water pills"), aliskiren-containing products (e.g. Rasilez®), or angiotensin converting enzyme inhibitors (ACEIs), or beta-blocker antihypertensive drugs.
- 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.
- Amantadine, an antiviral drug.
- Amphotericin B, an antifungal drug.
- Anticancer drugs, including cyclophosphamide and methotrexate. Amifostine, sometimes taken with anticancer drugs.
- Antidepressants, in particular selective serotonin reuptake inhibitors (SSRIs), including citalopram, escitalopram, and sertraline.
- Antidiabetic drugs, including insulin and oral medicines.
- Baclofen, which is used to treat muscle spasms caused by certain conditions.
- Bile acid resins used to lower cholesterol.
- Other blood pressure lowering drugs. When taken in combination with TEVETEN® PLUS, they may cause excessively low blood pressure.
- Calcium or vitamin D supplements.
- Corticosteroids used to treat joint pain and swelling.
- Diazoxide, an agent which increases glucose levels in the blood.
- Digoxin, a heart medication.
- 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.
- Heparin, a blood thinner.
- Lithium used to treat bipolar disease.
- Metformin, used for the treatment of type 2 diabetes.
- Nonsteroidal anti-inflammatory drugs (NSAIDs), used to reduce pain and swelling. Examples include ibuprofen, naproxen, celecoxib and indometacin.

- Skeletal muscle relaxants used to relieve muscle spasms, including tubocurare.
- Antibiotic drugs, e.g. Penicillin G, erythromycin, trimethoprim.
- Salicylic acid derivatives.
- Pentamidine, an antiparasitic agent.

PROPER USE OF THIS MEDICATION

Take TEVETEN® PLUS exactly as prescribed. It is recommended to take your dose at about the same time every day.

Usual Adult Dose:

Follow the doctor's instructions about how and when to take your medicine. The usual dose is one 600 mg/12.5 mg tablet once a day.

Please read the label carefully. If you have any questions about your medicine and how to take it, please ask your doctor or pharmacist.

Do not take TEVETEN® PLUS exceeding recommended dosage.

TEVETEN® PLUS can be taken with or without food. If TEVETEN® PLUS causes upset stomach, take it with food or milk. However, it should be taken consistently with respect to food intake, and at the same time everyday.

Keep taking your medicine for as long as the doctor tells you. Generally the treatment for high blood pressure is lifelong. Well before your prescription is finished, it is important to follow-up with your doctor to get another one. Try not to run out of your medications. Continue to follow the doctor's instructions.

Overdose:

If you think you have taken too much TEVETEN® 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:
- back, joint or leg pain, muscle cramps, spasms and pain, weakness, restlessness, gout
- dizziness, pins and needles in your fingers, headache
- constipation, diarrhea, nausea, vomiting, decreased appetite, anorexia, upset stomach, enlargement of the glands in your mouth
- bleeding under the skin, rash, red patches on the skin
- drowsiness, insomnia, anxiety, nervousness
- reduced libido
- cough, rhinitis (inflammation of the mucous membrane of the nose), aches in the joints or muscles, tiredness

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

TEVETEN® 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		√	
	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		√	
Uncommon	**Allergic Reaction:** rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing			√

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	
	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		√	
	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		√	
Rare	**Decreased Platelets:** bruising, bleeding, fatigue and weakness		√	
	Pulmonary edema: Fluid accumulated in the lung, symptoms like shortness of breath upon exertion, difficulty breathing, coughing.		√	
Very rare	**Toxic Epidermal Necrolysis:** severe skin peeling, especially in mouth and eyes			√

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	
Unknown	**Eye disorders:** **- Myopia:** sudden near sightedness or blurred vision **- Glaucoma:** increased pressure in your eyes, eye pain **- Choroidal effusion:** blind spots, eye pain, blurred vision			√
	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		√	
	Systemic Lupus erythematosus: Symptoms like fever, malaise, joint pains, myalgias, fatigue and temporary loss of cognitive ability		√	

This is not a complete list of side effects. For any unexpected effects while taking TEVETEN® PLUS, contact your doctor, nurse, or pharmacist.

HOW TO STORE IT

The expiry date of this medicine is printed on the label. Keep your tablets in their original package at 15 – 25°C. Protect from moisture.

Keep out of reach and sight of children.

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 (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.

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

The most recent version of this document plus the full Product Monograph, prepared for health professionals can be found at:

www.mylan.ca

or by contacting the sponsor, BGP Pharma ULC, Etobicoke, Ontario, M8Z 2S6 at:

1-844-596-9526

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