PART III: CONSUMER INFORMATION

PrTEVETEN®

eprosartan mesylate tablets

This leaflet is part III of a three-part "Product Monograph" published when TEVETEN® was approved for sale in Canada and is designed specifically for Consumers. Read this leaflet carefully before you start taking TEVETEN® and each time you get a refill. This leaflet is a summary and will not tell you everything about TEVETEN®. Talk to your doctor, nurse, or pharmacist about your medical condition and treatment and ask if there is any new information about TEVETEN®.

ABOUT THIS MEDICATION

What the medication is used for:

TEVETEN® is used for the treatment of high blood pressure.

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 failure 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:

TEVETEN® is an angiotensin receptor blocker (ARB). You can recognize an ARB because its medicinal ingredient ends in "**-SARTAN**".

This medicine does not cure your disease. It helps to control it. Therefore, it is important to continue taking TEVETEN® regularly even if you feel fine.

When it should not be used:

Do not take TEVETEN® if you:

- are allergic to eprosartan mesylate or to any non-medicinal ingredient in the formulation.
- have experienced an allergic reaction with swelling of the 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.
- are pregnant or intend to become pregnant. Taking TEVETEN® during pregnancy can cause injury and even death to your baby.
- are breastfeeding. It is possible that TEVETEN® passes into breast milk.
- have previously taken TEVETEN® and became unwell. Be sure to tell your doctor, nurse, or pharmacist that this has happened to you.
- 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 is:

Eprosartan mesylate

What the non-medicinal ingredients are:

Croscarmellose sodium (only in the 400 mg tablet), crospovidone (only in the 600 mg tablet), hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, pregelatinized starch, titanium dioxide, iron oxide red, iron oxide yellow, and polysorbate 80.

What dosage forms it comes in:

- 400 mg light to moderately pink, oval film-coated tablets
- 600 mg white, capsule-shaped film-coated tablets

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions - Pregnancy

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

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

- have experienced an allergic reaction to any drug used to lower blood pressure.
- have narrowing of a heart valve, heart or blood vessel disease.
- have diabetes, liver or kidney disease.
- 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" that makes your body keep potassium), or other medicines that may increase serum potassium.
- are on a low-salt diet.
- are on dialysis.
- are less than 18 years old.
- you are taking other medicines to control blood pressure.
- are taking a medicine that contains aliskiren, such as Rasilez®, used to lower high blood pressure. The combination with TEVETEN® is not recommended.
- are taking an angiotensin converting enzyme inhibitor (ACEI). You can recognize ACEIs because their medicinal ingredient ends in '-**PRIL**'.
- you produce too much of a hormone called aldosterone.
- you have been told by your doctor that you have an intolerance to some sugars.

Driving and using machines: Before you perform tasks which may require special attention, wait until you know how you respond to TEVETEN®. 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®:

- 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").
- blood pressure-lowering drugs, including diuretics ("water pills"), aliskiren-containing products (e.g. Rasilez®), or angiotensin converting enzyme inhibitors (ACEIs).
- lithium used to treat mood disorder.
- nonsteroidal anti-inflammatory drugs (NSAIDs), used to reduce pain and swelling. Examples include ibuprofen, naproxen, celecoxib, and indometacin.
- antibiotic drugs, such as trimethoprim.
- blood thinner drugs, such as heparin.

PROPER USE OF THIS MEDICATION

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

Usual adult dose:

Follow the doctor's instructions about how and when to take your medicine. The doctor will decide how many tablets you need to take each day and for how long.

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

This medicine is for the person named by the doctor. **Never** give it to others.

TEVETEN® can be taken with or without food, but it should be taken consistently with respect to food intake and at the same time every day. TEVETEN® should be swallowed with water.

Keep taking your medicine for as long as the doctor tells you. It may be necessary for the doctor to increase or decrease the dose. Your tablets may look different (colour/shape) if the dose is changed. Continue to follow the doctor's instructions.

Overdose:

If you think you have taken too much TEVETEN® 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 or leg pain, muscle cramps
- headache
- diarrhea, vomiting
- rash
- drowsiness, insomnia
- dizziness
- lightheadedness
- cough
- rhinitis
- fatigue, weakness or tiredness
- joint pain (arthralgia).

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	**Liver Disorder:** yellowing of the skin or eyes, dark urine, abdominal pain, nausea, vomiting, loss of appetite		√	
	Low Blood Pressure: dizziness, fainting, lightheadedness	√		
Uncommon	**Allergic Reaction:** rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing			√
	Rhabdomyolysis: muscle pain that you cannot explain, muscle tenderness or weakness, dark brown urine		√	

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
	Kidney Disorder: change in frequency of urination, nausea, vomiting, swelling of extremities, fatigue		√	
	Decreased White Blood Cells: infections, fatigue, fever, aches, pains, and flu-like symptoms		√	

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

HOW TO STORE IT

Keep out of reach and sight of children.

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

Please return any left over medicine to the pharmacist.

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 on line at:**
https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html
- **Call toll-free at 1-866-234-2345**
- **Complete a Canada Vigilance Reporting Form and:**
  - **Fax toll-free to 1-866-678-6789**
  - **Mail to: Canada Vigilance Program**
    Health Canada
    Postal Locator 1908C
    Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at
https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html

NOTE: Should you require information related to the management of side effects, contact your health professional. 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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