

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. This leaflet is a summary and will not tell you everything about TEVETEN. Contact your doctor or pharmacist if you have any questions about the drug.

Please read this leaflet before you start to take your medicine. Keep this leaflet until you have finished all your tablets. You may want to read it again. If you are helping someone else to take TEVETEN read this leaflet before you give the first tablet.

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 belongs to a group of drugs known as angiotensin II antagonists, which help to control high blood pressure. Angiotensin II, a natural hormone produced by the body, helps to keep blood pressure normal. One function of angiotensin II is to increase blood pressure, usually when it becomes too low. TEVETEN works by blocking the effect of angiotensin II, and as a result blood pressure is lowered.

When it should not be used:

You should not take TEVETEN if:

- ✓ If you are allergic to TEVETEN or any components of this formulation (see "What the important nonmedicinal ingredients are").
- ✓ If you are pregnant. When used in pregnancy, drugs like TEVETEN can cause fetal injury or death. Therefore, it is very important that you notify your doctor immediately if you are pregnant or plan to become pregnant.
- ✓ If you are breast feeding.
- ✓ TEVETEN should not be used in patients with certain kidney diseases (discuss with your doctor).
- ✓ If you have previously taken TEVETEN and become unwell, you should tell the doctor.
- ✓ If you have recently taken or are taking any other medicines, tell the doctor before you start taking TEVETEN.

What the medicinal ingredient is:

Eprosartan mesylate

What the important nonmedicinal 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:

Tablets, 400 mg and 600 mg strengths.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

TEVETEN should not be used during pregnancy. If you discover that you are pregnant while taking TEVETEN, you should immediately discuss stopping this medication with your doctor.

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

- you are taking other medicines to control blood pressure.
- you are pregnant, think you may be pregnant or thinking of becoming pregnant. Taking TEVETEN during pregnancy can cause injury and even death to your baby. This medicine should not be used during pregnancy. If you become pregnant or are planning to become pregnant while taking TEVETEN, discuss stopping this medication with your doctor immediately.
- you are breast feeding. It is known that TEVETEN does pass into animal milk. It is possible that TEVETEN passes into breast milk. You should not take these tablets when breast feeding.
- you have any heart, liver or kidney problems. Tell your doctor before you start taking your tablets.
- you have been told by your doctor that you have an intolerance to some sugars. Contact your doctor before taking this medicinal product.

INTERACTIONS WITH THIS MEDICATION

Be sure to tell your doctor about all other prescription and non-prescription medicines you are taking, in particular:

- diuretics (water pills)
- potassium-sparing diuretics
- potassium supplements
- lithium salts

PROPER USE OF THIS MEDICATION

Usual 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.

Remember 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 have taken more tablets than the recommended dose, tell a doctor immediately. Show the doctor your pack of tablets.

Missed Dose:

If you forget to take a tablet, take it as soon as you remember. Take your next dose at the normal time. Do not take two doses within 6 hours of each other.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, TEVETEN may cause unintended reactions, so-called side effects. Although most patients do not experience side effects when taking TEVETEN, some patients may experience headache, dizziness, lightheadedness, cough, aches in the joints or muscles, fatigue, weakness, or tiredness. If you develop any unusual discomfort, tell the doctor as soon as possible.

Side effects such as myalgia (muscle pain), myasthenia (muscle weakness), myositis (muscle inflammation) and rhabdomyolysis (a muscle-wasting disease, in rare cases leading to kidney failure), have been reported with the use of angiotensin receptor blockers, the class of drugs to which TEVETEN belongs. You should contact your physician promptly if you experience muscle pain that you cannot explain, muscle tenderness or weakness, or if you notice dark/brown urine.

Allergic reactions have been reported very rarely with TEVETEN. If you develop difficulty breathing or swallowing; or experience swelling of the face, lips and/or tongue, stop taking TEVETEN and seek medical attention immediately.

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

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
very rare	allergic reactions			√
	dark/brown urine		√	
	muscle inflammation		√	
	muscle pain		√	
	muscle weakness		√	

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

HOW TO STORE IT

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.

Store all medicines out of reach of children – preferably in a locked cupboard. Please return any left over medicine to the pharmacist.

REPORTING SUSPECTED SIDE EFFECTS

To monitor drug safety, Health Canada through the Canada Vigilance Program collects information on serious and unexpected side effects of drugs. If you suspect you have had a serious or unexpected reaction to this drug you may notify Canada Vigilance:

By toll-free telephone: 866-234-2345
By toll-free fax: 866-678-6789
Online: www.healthcanada.gc.ca/medeffect
By email: CanadaVigilance@hc-sc.gc.ca

By regular mail:
Canada Vigilance National Office
Marketed Health Products Safety and Effectiveness
Information Bureau
Marketed Health Products Directorate
Health Products and Food Branch
Health Canada
Tunney's Pasture, AL 0701C
Ottawa ON K1A 0K9

NOTE: Should you require information related to the management of the side effect, please contact your health care provider before notifying Canada Vigilance. 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.hc-sc.gc.ca> (Drug Product Database) or by contacting the sponsor, Abbott Laboratories, Limited, at: 1-800-268-4276

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