

## INFORMATION FOR THE CONSUMER

### **TEVETEN<sup>®</sup> PLUS (600 mg eprosartan as eprosartan mesylate and 12.5 mg hydrochlorothiazide) Tablets**

#### **Serious Warnings and Precautions**

**TEVETEN<sup>®</sup> PLUS should not be used during pregnancy. If you discover that you are pregnant while taking TEVETEN<sup>®</sup> PLUS, you should immediately discuss stopping this medication with your doctor.**

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<sup>®</sup> PLUS read this leaflet before you give the first tablet.

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

You must follow the doctor's advice and take the tablets as instructed. If there is anything that you do not understand please ask your doctor or pharmacist.

**Always keep medicines out of reach of children.** Return any left-over medicines to the pharmacist.

#### **What is TEVETEN<sup>®</sup> PLUS?**

TEVETEN<sup>®</sup> PLUS is used for the treatment of high blood pressure. It contains the active ingredients eprosartan mesylate and hydrochlorothiazide. TEVETEN<sup>®</sup> PLUS also contains the following non-medicinal ingredients: microcrystalline cellulose, lactose monohydrate, pregelatinized starch, crospovidone, magnesium stearate, polyvinyl alcohol, macrogol 3350, talc, titanium dioxide, iron oxide black, and iron oxide yellow. If you are on a special diet, or if you are allergic to any substance (including thiazides or sulphamethoxazole based drugs), ask your doctor or pharmacist whether any of these ingredients may cause a problem. It is also important for your doctor and pharmacist to know what other medications, herbal products and other non-prescription medications that you are taking.

TEVETEN<sup>®</sup> PLUS is a combination of an angiotensin II antagonist (eprosartan mesylate) and a diuretic (hydrochlorothiazide).

Angiotensin II is a natural hormone produced by the body that functions by tightening the blood vessels, and thus increases blood pressure when it becomes too low. Eprosartan, contained in TEVETEN<sup>®</sup> PLUS, works by blocking the effect of angiotensin II, and as a result lowers blood pressure. Hydrochlorothiazide, a thiazide diuretic, works by making the kidneys pass more water and salt. Together, eprosartan and hydrochlorothiazide lower high blood pressure.

### **What is hypertension?**

Hypertension is the medical term for 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 causes hypertension?**

In most cases, the root cause of hypertension is not known, although there are several factors which increase the risk of developing the disease. The most common risk factors include family history, age, race, weight, drinking and smoking. Hypertension is a long-term condition, often without symptoms in the early stages of this condition.

### **Before taking TEVETEN<sup>®</sup> PLUS, you should tell your doctor:**

- ✓ If you are taking other medicines, herbal remedies or nonprescription drugs. These include other medications for high blood pressure, arthritis medications, diabetic medications, etc.
- ✓ If you are pregnant, think you may be pregnant or thinking of becoming pregnant. Taking TEVETEN<sup>®</sup> PLUS 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<sup>®</sup> PLUS, discuss stopping this medication with your doctor immediately.
- ✓ If you are breast feeding. It is known that the medicinal ingredients of TEVETEN<sup>®</sup> PLUS (eprosartan and hydrochlorothiazide) pass into breast milk. You should not take these tablets when breast feeding.
- ✓ If you have any heart, liver or kidney problems before you start taking your tablets.

- ✓ If you are taking potassium supplements or salt substitutes containing potassium consult your doctor.
- ✓ If you have diabetes you may need to initially watch your blood sugar more closely when using TEVETEN<sup>®</sup> PLUS.
- ✓ If you are on lithium you need to watch your lithium levels more closely.
- ✓ If you have experienced any bad, unusual symptoms, or allergic reaction to TEVETEN<sup>®</sup> PLUS, eprosartan or hydrochlorothiazide.

**You should NOT take TEVETEN<sup>®</sup> PLUS if:**

- ✓ You are allergic to any component of TEVETEN<sup>®</sup> PLUS (see **What is TEVETEN<sup>®</sup> PLUS?**). You may have allergic symptoms if you have ever reacted to thiazides or sulpha drugs in the past.
- ✓ You are pregnant. When used in pregnancy, drugs like TEVETEN<sup>®</sup> PLUS 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.
- ✓ You are breast feeding.
- ✓ You have kidney problems.

**How to take TEVETEN<sup>®</sup> PLUS?**

**Usual dosage**

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.

TEVETEN<sup>®</sup> PLUS can be taken with or without food but 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.

**What happens if a dose is missed?**

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.

**If you take too many tablets:**

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

**Information on possible side-effects:**

Like all medicines, TEVETEN<sup>®</sup> PLUS may cause unintended reactions, so-called side effects. Although most patients do not experience side effects when taking TEVETEN<sup>®</sup> PLUS, some patients may experience headache, dizziness, lightheadedness, rash, cough, aches in the joints or muscles, fatigue, weakness, tiredness, low blood pressure, or fainting. 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 a component of TEVETEN<sup>®</sup> PLUS belongs. You should contact your physician promptly if you experience muscle pain that you cannot explain, muscle tenderness or weakness, or when you notice dark/brown urine.

Allergic reactions have been reported very rarely with eprosartan. If you develop difficulty breathing or swallowing; or experience swelling of the face, lips and /or tongue, stop taking TEVETEN<sup>®</sup> PLUS and contact your doctor immediately.

**How to store TEVETEN<sup>®</sup> PLUS?**

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.

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