PATIENT INFORMATION Tekturna® (pronounced tek-turn-a)

(aliskiren)

Tablets

Dosing Strengths: 150 mg tablets 300 mg tablets

Available by Prescription Only

Please read all of the available information before you start taking Tekturna. This leaflet does not take the place of talking with your doctor about your condition and treatment. If you have any questions about Tekturna, ask your doctor or pharmacist, visit www.Tekturna.com, or call 1-888-Tekturna (1-888-835-8876).

IMPORTANT WARNING: If you get pregnant, stop taking Tekturna and call your doctor right away. Tekturna may harm an unborn baby, causing injury and even death. If you plan to become pregnant, talk to your doctor about other treatment options before taking Tekturna.

What Is High Blood Pressure (Hypertension)?

Blood pressure is the force that pushes the blood through your blood vessels to all the organs of your body. You have high blood pressure when the force of your blood moving through your blood vessels is too great. Renin (pronounced REE-nin) is a chemical in the body that starts a process that makes blood vessels narrow, leading to high blood pressure.

High blood pressure makes the heart work harder to pump blood throughout the body and causes damage to the blood vessels. If high blood pressure is not treated, it can lead to stroke, heart attack, heart failure, kidney failure, and vision problems.

What Is Tekturna?

Tekturna is a type of prescription medicine called a direct renin inhibitor that works in the body to help lower blood pressure (hypertension).

How Does Tekturna Work?

Tekturna reduces the effect of renin and the harmful process that narrows blood vessels. Tekturna helps blood vessels relax and widen so blood pressure is lowered.

Who Should Not Take Tekturna?

- If you get pregnant, stop taking Tekturna and call your doctor right away. If you plan to become pregnant, talk to your doctor about other treatment options for your high blood pressure.
- Do not take Tekturna if you are allergic to any of its ingredients.

Aliskiren is the active ingredient in Tekturna. The inactive ingredients (the ingredients that bind the tablet together) are colloidal silicon dioxide, crospovidone, hypromellose, iron oxide colorants, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, talc, and titanium dioxide. These inactive ingredients are considered safe and are commonly used in many medications. Talk to your doctor if you have questions.

Tekturna has not been studied in children under 18 years of age.

What Should I Tell My Doctor Before Taking Tekturna?

Tell your doctor about all your medical conditions, including whether you:

- are pregnant or planning to become pregnant.
- are breast-feeding. It is not known if Tekturna passes into your breast milk. You should choose either to take Tekturna or breast-feed, but not both.
- have kidney problems.
- are allergic to any of the ingredients in Tekturna.

Tell your doctor about all the medicines you take including prescription and nonprescription medicines, vitamins and herbal supplements. Especially tell your doctor if you are taking:

- other medicines for high blood pressure or a heart problem.
- water pills (also called "diuretics").
- medicines for treating fungus or fungal infections.
- cyclosporine (a medicine used to suppress the immune system).
- potassium-containing medicines, potassium supplements, or salt substitutes containing potassium.

Your doctor or pharmacist will know what medicines are safe to take together.

How Should I Take Tekturna?

• Take Tekturna once a day, at the same time each day. As with any blood pressure medication, it is important to take Tekturna on a regular daily basis exactly as prescribed by your doctor.

- Tekturna can be taken by itself or safely in combination with other medicines to lower high blood pressure. It can also be safely taken in combination with medications for other conditions such as high cholesterol or diabetes. Your doctor may change your dose if needed
- Tekturna can be taken with or without food.

If you miss a dose, take it as soon as you remember. If it is close to your next dose, do not take the missed dose. Just take the next dose at your regular time. If you take too much Tekturna, call your doctor or Poison Control Center, or go to the nearest hospital emergency room.

What Are Possible Side Effects Of Tekturna?

Tekturna may cause the following serious side effect:

• Low blood pressure (hypotension). Your blood pressure may get too low if you also take water pills, are on a low-salt diet, get dialysis treatments, have heart problems, or get sick with vomiting or diarrhea. Lie down if you feel faint or dizzy. Call your doctor right away.

Side effects were usually mild and brief. Few patients decided to stop taking Tekturna because of side effects. In clinical studies, the most common side effect experienced by more patients taking Tekturna than patients taking a sugar pill (placebo) was diarrhea. Other less common reactions to Tekturna include cough, and rash.

If you develop an allergic reaction involving swelling of the face, lips, throat and/or tongue which may cause difficulty in breathing and swallowing, stop taking Tekturna and contact your doctor immediately.

For a complete list of side effects, ask your doctor or pharmacist. Tell your doctor if you get any side effect that bothers you or will not go away.

How Do I Store Tekturna?

- Store Tekturna tablets at room temperature between 59° to 86°F.
- Keep Tekturna in the original prescription bottle in a dry place. Do not remove the desiccant (drying agent) from the bottle.
- Keep Tekturna and all medicines out of the reach of children.

General Information About Tekturna

Do not give Tekturna to other people, even if they have the same condition or symptoms you have. It may harm them.

This leaflet summarizes the most important information about Tekturna.

For more information about Tekturna, ask your doctor or pharmacist, visit www.Tekturna.com, or call 1-888-Tekturna (1-888-835-8876).

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