

## **PATIENT INFORMATION**

### **Tekturna® (tek-turn-a) (aliskiren) Tablets**

Read the Patient Information that comes with Tekturna before you start taking it and each time you get a refill. There may be new information. This leaflet does not replace talking to your doctor about your condition or treatment. If you have any questions about Tekturna, ask your doctor or pharmacist.

#### **What is the most important information I should know about Tekturna?**

**Tekturna can cause harm or death to an unborn baby. Talk to your doctor about other ways to lower your blood pressure if you plan to become pregnant. If you get pregnant while taking Tekturna, tell your doctor right away.**

#### **What Is Tekturna?**

Tekturna can help your blood vessels relax and widen so blood pressure is lower. Tekturna is a type of prescription medicine called a direct renin inhibitor (DRI). By reducing renin, it helps to reduce blood pressure.

#### **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. Drugs that lower blood pressure lower your risk of having a stroke or heart attack.

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.

#### **Who Should Not Take Tekturna?**

##### **Do 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.
- you have diabetes and are taking a kind of medicine called an angiotensin receptor blocker (ARB) or angiotensin-converting enzyme inhibitor (ACEI).
- you are allergic to any of its ingredients. See the end of this leaflet for a complete list of the ingredients in Tekturna.
- 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:**

- have kidney problems.
- are pregnant or planning to become pregnant, see **"What is the most important information I should know about Tekturna?"**
- are breastfeeding. It is not known if Tekturna passes into your breast milk. You should choose to either take Tekturna or breastfeed, but not both.
- are allergic to any of the ingredients in Tekturna, see **"What are the ingredients in Tekturna?"**

- have ever had an allergic reaction (called angioedema) to another blood pressure medicine. Symptoms may include: swelling of the face, lips, tongue, throat, arms, and legs, and may cause difficulty breathing (angioedema).
- have any other medical problems

**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:**

- a kind of medicine to control blood pressure called angiotensin receptor blocker (ARB) or angiotensin-converting enzyme inhibitor (ACEI).
- simvastatin (Zocor®) or atorvastatin (Lipitor®) (medicines to lower cholesterol in your blood).
- medicines used to lower blood pressure, water pills (also called “diuretics”), especially potassium-sparing diuretics.
- medicines for treating fungus or fungal infections (like itraconazole or ketoconazole).
- Cyclosporine (Gengraf®, Neoral, Sandimmune), (a medicine used to suppress the immune system).
- potassium-containing medicines, potassium supplements, or salt substitutes containing potassium.
- nonsteroidal anti-inflammatory drugs (NSAIDs) (like ibuprofen or naproxen), including selective Cyclooxygenase-2 inhibitors (COX-2 inhibitors).

Ask your doctor if you are not sure whether you are taking one of the medicines listed above. Know the medicines you take. Keep a list of them to show your doctor or pharmacist when you get a new medicine. 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. 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 serious side effects:

- **Harm to an unborn baby causing injury or death. See “What is the most important information I should know about Tekturna?”**
- **Severe Allergic Reactions and Angioedema (hypersensitivity).** Aliskiren may cause difficulty breathing or swallowing, tightness of the chest, hives, general rash, swelling, itching, dizziness, vomiting, or abdominal pain (signs of a severe allergic reaction called anaphylactic reaction). Aliskiren can also cause swelling of the face, lips, tongue, throat, arms and legs or the whole body (signs of angioedema). Stop taking Tekturna and get

medical help right away and tell your doctor if you get any one or more of these symptoms. Angioedema can happen at any time while you are taking Tekturna.

- **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.**
- **Renal impairment or failure.** Aliskiren may cause renal disorder with symptoms such as severely decreased urine output or decreased urine output (signs of renal impairment or failure).

**Common side effects of Tekturna include:**

- diarrhea
- cough
- dizziness
- headache
- flu-like symptoms
- tiredness
- high levels of potassium in the blood (hyperkalemia)

Less common side effects include rash, severe skin reactions (signs may include severe blistering of the lips, eyes or mouth, rash with fever and skin peeling), liver disorder (signs may include nausea, loss of appetite, dark colored urine or yellowing of skin and eyes) and low level of sodium in blood.

Tell your doctor if you have any side effect that bothers you or that does not go away. These are not all of the possible side effects of Tekturna. For a complete list of side effects, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

**How Do I Store Tekturna?**

- Store Tekturna tablets at room temperature between 59°F and 86°F (15°C and 30°C).
- 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**

Medicines are sometimes prescribed for conditions not listed in the patient information leaflet. Do not take Tekturna for a condition for which it was not prescribed. 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. If you have more questions about Tekturna talk with your doctor or pharmacist. You can ask your doctor or pharmacist for information that is written for healthcare professionals.

**For more information about Tekturna, ask your doctor or pharmacist, visit [www.Tekturna.com](http://www.Tekturna.com), or call 1-844-399-5701.**

**What are the ingredients in Tekturna?**

Active Ingredients: aliskiren hemifumarate

Inactive Ingredients: colloidal silicone dioxide, crospovidone, hypromellose, iron oxide colorants, magnesium stearate, microcrystalline cellulose, polyethylene glycol, talc, and titanium dioxide.

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