

## FDA approved patient labeling

### PATIENT INFORMATION

Tekturna (pronounced tek-turn-a)

(aliskiren)

Tablets

Dosing Strengths:

150 mg tablets

300 mg tablets

Available by Prescription Only

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.

**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 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. 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?

- **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. 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:

- are pregnant or planning to become pregnant, see IMPORTANT WARNING
- 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, see “what are the ingredients in Tekturna”
- have ever had a reaction called angioedema, to an ACE inhibitor medicine. Angioedema causes swelling of the face, lips, tongue, throat, arms, and legs, and may cause difficulty breathing.

**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.
- Atorvastatin (medicine to lower cholesterol in your blood).
- 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. 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:

- **Injury or death to an unborn baby. See IMPORTANT WARNING.**
- **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.
- **Angioedema:** Aliskiren can cause swelling of the face, lips, tongue, throat, arms and legs or the whole body. 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.

Common side effects of Tekturna include:

- diarrhea
- cough
- dizziness
- headache
- flu-like symptoms
- back pain

tiredness

Less common side effects include rash.

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.

### **How Do I Store Tekturna?**

- Store Tekturna tablets at room temperature between 59° to 86°F (15°-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. 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 1-888-Tekturna (1-888-835-8876).**

### **What are the ingredients in Tekturna?**

Active Ingredients: Aliskiren (Tekturna)

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

Manufactured by:

Novartis Pharma AG, Stein, Switzerland

Novartis Pharma Produktions GmbH, Wehr, Germany

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Novartis Pharmaceuticals Corporation

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