

FDA-Approved Patient Labeling

Patient Information

**Tekturna HCT[®] (tek-turn-a HCT)
(aliskiren and hydrochlorothiazide, USP)
Combination Tablets**

Read the Patient Information that comes with Tekturna HCT before you start taking it and each time you get a refill. There may be new information. This leaflet does not take the place of talking with your doctor about your condition and treatment.

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

Tekturna HCT 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 HCT, tell your doctor right away.

What is Tekturna HCT?

Tekturna HCT contains two prescription medicines in one tablet that work together to lower blood pressure. It contains:

- aliskiren (Tekturna), a direct renin inhibitor (DRI)
- hydrochlorothiazide, a diuretic (water pill)

Aliskiren (Tekturna) reduces the effect of renin, and the harmful process that narrows blood vessels. Aliskiren also helps blood vessels relax and widen so blood pressure is lower. Hydrochlorothiazide reduces the amount of salt and water in your body so your blood pressure is lower.

Tekturna HCT may be used to lower high blood pressure in adults

- when one medicine to lower high blood pressure is not enough
- as the first medicine to lower high blood pressure if your doctor decides that you are likely to need more than one medicine

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

Your doctor may prescribe other medicines for you to take along with Tekturna HCT to treat your high 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. One cause of high blood pressure is renin, a chemical in the body that starts a process that makes blood vessels narrow, leading to high blood pressure.

Tekturna HCT reduces high blood pressure. Medicines that lower your blood pressure lower your chance 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 HCT?

- **If you get pregnant, stop taking Tekturna HCT 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.**

- **If you have diabetes and are taking a kind of medicine called an angiotensin-receptor-blocker or angiotensin-converting-enzyme-inhibitor.**
- **Do not take Tekturna HCT if you make very little or no urine due to kidney problems.**
- **Do not take Tekturna HCT if you are allergic to any of its ingredients. See the end of this leaflet for a complete list of the ingredients in Tekturna HCT.**

What should I tell my doctor before taking Tekturna HCT?

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 HCT?
- have any allergies or asthma
- have liver problems
- have systemic lupus erythematosus (SLE). Tekturna HCT can make your SLE active or worse.
- 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.
- are breast-feeding. It is not known if Tekturna HCT passes into your breast milk.

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 called angiotensin receptor blocker or angiotensin converting enzyme inhibitor
- 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
- cholestyramine (for example; Questran, Questran Light, Cholestyramine Light, Locholest Light, Locholest, Prevalite) (medicines to lower the cholesterol in your blood)
- colestipol (for example; Colestipol hydrochloride, Colestid, Flavored Colestid) (medicines to lower the cholesterol in your blood)
- medicines to treat diabetes, including insulin
- lithium, a medicine used in some types of depression. Do not take Tekturna HCT if you are taking lithium.
- Nonsteroidal anti-inflammatory (NSAIDs) medicines. Ask your doctor if you are not sure if you are taking one of these medicines.
- blood thinners
- barbiturate or narcotic medicines. Ask your doctor if you are not sure if you are taking one of these medicines.

Your doctor or pharmacist will know what medicines are safe to take together. Know your medicines. Keep a list of your medicines and show it to your doctor or pharmacist when you get a new medicine.

How should I take Tekturna HCT?

- Take Tekturna HCT exactly as prescribed by your doctor. It is important to take Tekturna HCT every day to control your blood pressure.
- Take Tekturna HCT once each day, about the same time each day.
- Take Tekturna HCT the same way everyday, either with or without a meal.
- Your doctor may change your dose of Tekturna HCT if needed.
- If you miss a dose of Tekturna HCT, 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 HCT, call your doctor or a Poison Control Center, or go to the nearest hospital emergency room.

What are the possible side effects of Tekturna HCT?

Tekturna HCT may cause serious side effects:

- **Injury or death to an unborn baby.** See What is the most important information I should know about Tekturna HCT?
- **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. Drinking alcohol and taking certain medicines (barbiturates or narcotics) can cause low blood pressure to get worse. Lie down if you feel faint or dizzy, and call your doctor right away.
- **Angioedema.** Aliskiren in Tekturna HCT 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 HCT.
- **Active or worsened Systemic Lupus Erythematosus (SLE).** If you have SLE, tell your doctor right away if you get any new or worse symptoms.
- **Eye problems.** One of the medicines in Tekturna HCT can cause eye problems that may lead to vision loss. Symptoms of eye problems can happen within hours to weeks of starting Tekturna HCT. Tell your doctor right away if you have:
 - Decrease in vision
 - Eye pain

Common side effects of Tekturna HCT include:

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

Other less common side effects include skin 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 HCT. For a complete list of side effects, ask your doctor or pharmacist.

How do I store Tekturna HCT?

- Store Tekturna HCT tablets at room temperature between 59°F-86°F (15°C-30°C).
- Keep Tekturna HCT in the original prescription bottle in a dry place. Do not remove the desiccant (drying agent) from the bottle.

Keep Tekturna HCT and all medicines out of the reach of children.

General information about Tekturna HCT

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

For more information about Tekturna HCT, visit www.TekturnaHCT.com, or call 1-888-669-6682.

What are the ingredients in Tekturna HCT?

Active ingredients: Aliskiren and hydrochlorothiazide

Inactive ingredients: Colloidal silicon dioxide, crospovidone, hydroxypropyl methylcellulose, iron oxide colorants, lactose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, talc, and titanium dioxide, and wheat starch

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



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