

Patient Information

Tekturna® HCT (tek-turn-a HCT) (aliskiren and hydrochlorothiazide) 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 2 prescription medicines in 1 tablet that work together to lower blood pressure. It contains:

- aliskiren (Tekturna), a direct renin inhibitor (DRI)
- hydrochlorothiazide (HCTZ), 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 1 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 1 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 of blood in your blood vessels when your heart beats and when your heart rests. You have high blood pressure when the force is too much.

High blood pressure makes the heart work harder to pump blood throughout the body and causes damage to blood vessels. Tekturna HCT can help your blood vessels relax so your blood pressure is lower. Medicines that lower your blood pressure may lower your chance of having a stroke or heart attack.

Who should not take Tekturna HCT?

Do 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.

- you have diabetes and are taking a kind of medicine called an angiotensin receptor blocker (ARB) or angiotensin-converting enzyme inhibitor (ACEI).
- you make very little or no urine due to kidney problems.
- you are allergic to aliskiren, hydrochlorothiazide, any of the other ingredients of Tekturna HCT listed at the end of this leaflet.
- Tekturna HCT has not been studied in children under 18 years of age

What should I tell my doctor before taking Tekturna HCT?

Before taking Tekturna HCT, tell your doctor if 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 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).
- are breastfeeding. It is not known if Tekturna HCT passes into your breast milk and if it can harm your baby.
- have any other medical problems

Tell your doctor about all the medicines you take, including prescription and nonprescription medicines, vitamins and herbal supplements. Tekturna HCT and certain other medicines may affect each other and cause side effects.

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)
- cholesterol-lowering medicines
 - simvastatin (Zocor®) or atorvastatin (Lipitor®)
 - cholestyramine (Questran, Questran Light, Cholestyramine Light, Locholest Light, Locholest, Prevalite)
 - colestipol (Colestipol hydrochloride, Colestid, Flavored Colestid)
- 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
- medicines used to treat diabetes, including insulin
- lithium, a medicine used in some types of depression
- medicines used to relieve pain or inflammation, especially 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 if you are taking one of these medicines.

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 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 every day, 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 should I avoid while taking Tekturna HCT?

Drinking alcohol. Drinking alcohol during treatment with Tekturna HCT can cause you to have low blood pressure. **See “What are the possible side effects of Tekturna HCT?”**

What are the possible side effects of Tekturna HCT?

Tekturna HCT 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 HCT?”**
- **Severe Allergic Reactions and Angioedema (hypersensitivity).** Aliskiren, one of the medicines in Tekturna HCT, can 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 HCT and get medical help right away. 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.
- **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.

- **Renal Impairment or Failure.** Aliskiren, one of the medicines in Tekturna HCT, may cause renal disorder with symptoms such as severely decreased urine output or decreased urine output (signs of renal impairment or failure).
- **Tekturna HCT may affect your potassium levels.** Your doctor will do blood tests to check your potassium levels.
- **Allergic reactions:** Hydrochlorothiazide, one of the medicines in Tekturna HCT, can cause allergic reactions.
- **Active or Worsened Systemic Lupus Erythematosus (SLE).** If you have SLE, tell your doctor right away if you get any new or worse symptoms. Possible signs of SLE are facial rash, joint pain, muscle disorder, fever.
- **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)
- vertigo
- arthralgia

Less common side effects include skin 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 HCT. 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 HCT?

- Store Tekturna HCT tablets at room temperature between 59°F to 86°F (15°C to 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 or pharmacist. You can ask your doctor or pharmacist for information that is written for healthcare professionals.

For more information about Tekturna HCT, visit www.Tekturna.com, or call 1-844-399-5701.

What are the ingredients in Tekturna HCT?

Active ingredients: aliskiren hemifumarate and hydrochlorothiazide

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

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