

## IMPORTANT SAFETY INFORMATION

**IMPORTANT WARNING: TEKTURNA (aliskiren) or TEKTURNA HCT (aliskiren and hydrochlorothiazide) 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 become pregnant, stop taking TEKTURNA or TEKTURNA HCT and tell your doctor right away.**

Administer or take TEKTURNA or TEKTURNA HCT as instructed by your Doctor. TEKTURNA should not be given to children under 2 years of age. The safety and effectiveness of TEKTURNA has not been established in pediatric patients younger than 6 years.

Do not take TEKTURNA or TEKTURNA HCT if you have diabetes and are taking a kind of medicine called an angiotensin receptor blocker (ARB) or angiotensin-converting enzyme inhibitor (ACEI); or if you are allergic to aliskiren or any of their other ingredients.

In addition, do not take TEKTURNA HCT if you make very little or no urine due to kidney problems, or if you have allergic reactions to certain medicines called sulfonamides or hydrochlorothiazide.

Aliskiren, a medicine in TEKTURNA and 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 angioedema). TEKTURNA and TEKTURNA HCT can also cause swelling of the face, lips, tongue, throat, arms and legs, or the whole body (signs of angioedema). Stop taking TEKTURNA or TEKTURNA HCT, 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 or TEKTURNA HCT.

Your blood pressure may get too low if you also:

- take water pills (also called "diuretics")
- are on a low-salt diet
- get dialysis treatments
- have heart problems
- get sick with vomiting or diarrhea
- drink alcohol and take certain medicines (barbiturates or narcotics). These can cause low blood pressure to get worse with TEKTURNA HCT.

Lie down if you feel faint or dizzy. Call your doctor or seek medical attention right away.

Tell your doctor about all of your medical conditions, including: if you have kidney problems; if you have ever had an allergic reaction, called angioedema, to another blood pressure medicine; or if you are breastfeeding. It is not known if TEKTURNA or TEKTURNA HCT passes into your breast milk and can harm your baby. You should not take TEKTURNA or TEKTURNA HCT and breastfeed.

Tell your doctor right away if you have eye pain or a decrease in vision.

Especially, tell your doctor about all the medicines you take, including a kind of medicine to control blood pressure, called an angiotensin receptor blocker (ARB) or ACE inhibitor (ACEI), cholesterol lowering medicines (like simvastatin, atorvastatin, cholestyramine, colestipol), water pills (especially potassium-sparing diuretics), medicines to treat fungal infections (like itraconazole or ketoconazole), cyclosporine, potassium-containing medicines, potassium supplements, salt substitutes containing potassium, or NSAIDs (like ibuprofen or naproxen), including Cyclooxygenase-2 inhibitors (COX-2 inhibitors), and non-prescription medicines, vitamins and herbal supplements.

Additionally, if you take TEKTURNA HCT, tell your doctor if you have liver problems, have allergies or asthma, have lupus, or if you take lithium or medicine to treat diabetes.

The most common side effects of TEKTURNA and TEKTURNA HCT include:

- diarrhea
- cough
- dizziness
- headache
- flu-like symptoms
- back pain
- tiredness
- high levels of potassium in the blood (hyperkalemia)
- vertigo
- joint pain (arthralgia)

Less common side effects include skin rash, severe skin reactions, liver disorder, and low level of sodium in blood.

Store this medicine at room temperature between 68°F to 77°F (20°C to 25°C) and keep out of reach of children. Keep in its original container and protect from moisture.

You are encouraged to report side effects of prescription drugs to the FDA.

**To report SUSPECTED ADVERSE REACTIONS, contact Noden Pharma USA Inc. at [Safety@nodenpharma.com](mailto:Safety@nodenpharma.com) or 1-844-399-5701 and/or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).**

Please see full [Prescribing Information](#) and [Patient Information](#), including **IMPORTANT WARNING**, for TEKTURNA.

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