

# Health Checkup: FDA Approves New Treatment For High Blood Pressure That Combines Three Medicines In A Single Pill



(NAPSA)—In the United States, high blood pressure remains a significant health epidemic with an estimated 75 million—or nearly 1 in 3—adults living with the condition. If left untreated, people with high blood pressure may experience an increased risk of cardiovascular events such as stroke or heart attack.

Adopting a healthy lifestyle is an effective first step in controlling high blood pressure. Here are a few steps you can take to help keep your blood pressure under control:

- Determine a blood pressure goal with your doctor. Because high blood pressure often doesn't have symptoms, your progress should be checked regularly

- Keep an eye on what you eat (e.g., fat intake). Changes in your food choices—both at home and when you dine out—can make a difference in your blood pressure

- Find alternatives for salt (sodium). Buy fewer processed foods and replace those favorite items with low-sodium versions

- Think outside the gym. Get involved in any physical activities that get you up and moving for at least 30 minutes, most days of the week (e.g., walk the dog, garden, play golf, try yoga)

- Keep appointments with your doctor. It is important to remember that with proper medical care, high blood pressure can be successfully managed

- If medication is prescribed, take it as directed

In addition to living a healthier life, many people will require medication, and up to 85% of high blood pressure patients will require more than one medication. While there are many medicines available to treat high blood pressure, recent data show over 30% of people being treated for this condition still have not reached the blood pressure goal recommended by their physicians.

The U.S. Food and Drug Administration (FDA) recently approved a new treatment option for doctors to consider when treating their hypertensive patients. This new medication, called AMTURNIDE™ (aliskiren, amlodipine and hydrochlorothiazide) tablets, is a prescription blood pressure treatment that combines three medicines in a single pill—TEKTURNA® (aliskiren), the only FDA approved direct-renin inhibitor, amlodipine, a widely-used

calcium channel blocker, and hydrochlorothiazide, a diuretic. AMTURNIDE is for patients whose blood pressure is not adequately controlled with any two of its individual components and is not indicated for initial therapy of high blood pressure.

The single-pill combination AMTURNIDE works to lower blood pressure in three ways. The TEKTURNA component targets the activity of the renin angiotensin aldosterone system (RAAS), an important regulator of blood pressure. TEKTURNA directly binds to and inhibits renin, an enzyme produced by the kidneys that starts a process that can make blood vessels narrow and lead to high blood pressure. The calcium channel blocker amlodipine lowers blood pressure by relaxing the muscles in the blood vessel walls, and the diuretic hydrochlorothiazide increases the excretion of sodium chloride and water. All three complementary medicines work to relax blood vessels and reduce blood volume, therefore lowering blood pressure.

Talk to your doctor about whether AMTURNIDE may be an appropriate treatment option for you. For more information and the full prescribing information, please visit [www.amturnide.com](http://www.amturnide.com).

## About AMTURNIDE

AMTURNIDE is indicated for the treatment of hypertension. AMTURNIDE is not indicated for initial therapy of hypertension.

Use AMTURNIDE for patients not adequately controlled with any two of the following: aliskiren, dihydropyridine calcium-channel blockers (DHP-CCB), and thiazide diuretics.

Switch a patient who experiences dose-limiting adverse reactions attributed to an individual component while on any dual combination of components of AMTURNIDE to AMTURNIDE at a lower dose of that component to achieve similar blood pressure reductions.

AMTURNIDE may be substituted for its titrated components.

Safety and efficacy of AMTURNIDE in pediatric patients have not been established.

## IMPORTANT SAFETY INFORMATION

**WARNING: AVOID USE IN PREGNANCY**  
When pregnancy is detected, discontinue AMTURNIDE as soon as possible.

**Drugs that act directly on the renin-angiotensin-aldosterone system can cause injury and even death to the developing fetus. [See WARNINGS and Precautions (5.1) and Use in Special Populations (8.1)]**

**Angioedema:** Angioedema of the face, extremities, lips, tongue, glottis and/or larynx has been reported in patients treated with aliskiren and has necessitated hospitalization and intubation. This may occur at any time during treatment and has occurred in patients with and without a history of angioedema with ACE inhibitors (ACEI) or angiotensin receptor antagonists. Discontinue AMTURNIDE immediately in patients who develop angioedema and do not readminister.

**Hypotension:** Excessive hypotension was seen rarely (0.3%) in patients with uncomplicated hypertension treated with AMTURNIDE in a controlled trial. Volume- and/or salt-depletion should be corrected in patients prior to administration of AMTURNIDE or symptomatic hypotension may occur.

**Risk of MI or Angina:** Rarely, initiation or change to the dose of a calcium channel blocker has resulted in the increased frequency, duration, or severity of angina or acute myocardial infarction, particularly in patients with severe obstructive coronary artery disease.

**Renal Considerations:** In patients with severe renal impairment (GFR <30mL/min), loop diuretics are preferred to thiazides, so AMTURNIDE is not recommended.

No data are available on the use of AMTURNIDE in patients with unilateral or bilateral renal artery stenosis. In studies of ACEIs in hypertensive patients with unilateral or bilateral renal artery stenosis, increases in serum creatinine or blood urea nitrogen have been reported.

**Hepatic Considerations:** Amlodipine is extensively metabolized by the liver. In patients with severe hepatic impairment, start amlodipine at 2.5 mg per day, a dose not available in AMTURNIDE.

**Patients with Heart Failure:** AMTURNIDE has not been studied in patients with heart failure.

**Serum Electrolyte Abnormalities:** In a short-term controlled trial, hypokalemia (serum potassium <3.5 mEq/L) was seen

in 11% of patients treated with AMTURNIDE. The incidence of hyperkalemia (serum potassium >5.5 mEq/L) was 3%. No patients treated with AMTURNIDE discontinued due to increase or decrease of serum potassium. Monitor serum electrolytes to detect possible electrolyte imbalance.

Concomitant use of AMTURNIDE with potassium-sparing diuretics, potassium supplements, or other salt substitutes containing potassium may lead to increases in serum potassium.

**Cyclosporine or Itraconazole:** Concomitant use of AMTURNIDE with cyclosporine or itraconazole is not recommended.

**Furosemide:** When aliskiren was coadministered with furosemide, the AUC and Cmax of furosemide were reduced by about 30% and 50%, respectively. Patients receiving furosemide could find its effect diminished after starting aliskiren.

**Important considerations due to the HCTZ component:** Uptitrate HCTZ slowly in patients with renal disease, as thiazides may precipitate azotemia. Titrate HCTZ gradually in patients with hepatic impairment, as minor fluid and electrolyte balance may precipitate hepatic coma. Hypersensitivity reactions to HCTZ may occur in patients with or without a history of allergy or bronchial asthma, but are more likely in patients with such a history. Thiazide diuretics have been reported to cause exacerbation or activation of systemic lupus erythematosus. Lithium generally should not be given with thiazides.

HCTZ, a sulfonamide, can cause an idiosyncratic reaction resulting in transient myopia and angle-closure glaucoma. Symptoms include acute onset of decreased visual acuity or ocular pain and typically occur within hours to weeks of drug initiation. Discontinue HCTZ as rapidly as possible in these patients. Risk factors for developing acute angle-closure glaucoma may include a history of sulfonamide or penicillin allergy.

**Common AEs:** The most common adverse events in a short-term controlled trial that occurred in at least 2% of patients treated with AMTURNIDE were peripheral edema (7.1%), dizziness (3.6%), headache (3.6%), and nasopharyngitis (2.6%).

**About TEKTURNA**  
TEKTURNA is a prescription medicine for adults used to treat high blood pressure. TEKTURNA may be used alone or in combination with other medicines to lower high blood pressure. TEKTURNA has not been adequately studied in combination with the maximum doses of a class of medicines called ACE inhibitors.

## IMPORTANT SAFETY INFORMATION

**IMPORTANT WARNING:**  
TEKTURNA may harm an unborn baby, causing injury and even death. 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 medicines to treat your high blood pressure before taking TEKTURNA.

Do not take TEKTURNA if you are allergic to any of its ingredients.

TEKTURNA 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. This reaction, called angioedema, can happen at any time while you are taking TEKTURNA.

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

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

Tell your doctor about all of your medical conditions, including kidney problems, or whether you have ever had angioedema to an ACE inhibitor medicine.

Also, tell your doctor about all medicines you take, including other medicines for high blood pressure or a heart problem, atorvastatin, water pills, cyclosporine, potassium-containing medicines, potassium supplements, or salt substitutes containing potassium, or medicines to treat fungal infections.

The most common side effects of TEKTURNA include:

- diarrhea
  - cough
  - dizziness
  - headache
  - flu-like symptoms
  - back pain
  - tiredness
- Less common side effects include rash.