

Patient Information

Amturnide™ (AM-turn-ide)

**Amturnide
(aliskiren, amlodipine and hydrochlorothiazide)
Tablets**

Read the Patient Information leaflet that comes with Amturnide 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 medical condition and treatment. If you have any questions about Amturnide, ask your doctor or pharmacist.

What is the most important information I should know about Amturnide?

Amturnide 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 Amturnide, tell your doctor right away.

What is Amturnide?

Amturnide is a prescription medicine used to lower blood pressure (hypertension). Amturnide is not for use as the first medicine to treat your high blood pressure.

Amturnide contains 3 different prescription medicines:

- aliskiren, a direct renin inhibitor (DRI)
- amlodipine, a calcium channel blocker (CCB) and
- hydrochlorothiazide (HCTZ), a diuretic (water pill)

It is not known if Amturnide is safe and works in children under 18 years of age.

Who should not take Amturnide?

Do not take Amturnide if you:

- If you get pregnant, stop taking Amturnide 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.
- have diabetes and are taking a kind of medicine called an angiotensin-receptor-blocker or angiotensin-converting-enzyme-inhibitor.
- have low or no urine output
- are allergic to any ingredients in Amturnide or other medicines that contain sulfonamide. See the end of this leaflet for a complete list of ingredients in Amturnide.

What should I tell my doctor before taking Amturnide?

Before taking Amturnide, tell your doctor if you:

- have kidney problems
- have liver problems
- have lupus
- have had an allergic reaction to another blood pressure medicine. Symptoms may include: swelling of the face, lips, tongue, throat, arms and legs, and trouble breathing.
- have any other medical problems
- are pregnant or planning to become pregnant. **See “What is the most important information I should know about Amturnide?”**

- are breast-feeding. It is not known if Amturnide passes into your breast milk and if it can harm your baby. You and your doctor should decide if you will take Amturnide or breastfeed. You should not do both.

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

Especially tell your doctor if you are taking:

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- a kind of medicine called angiotensin receptor blocker or angiotensin converting enzyme inhibitor
- water pills (also called “diuretics”)
- medicines for treating fungus or fungal infections
- cyclosporine (Gengraf[®], Neoral, Sandimmune), a medicine used to suppress the immune system
- potassium-containing medicines, potassium supplements, or salt substitutes containing potassium
- cholesterol lowering medicines
 - atorvastatin (Lipitor[®])
 - cholestyramine (Questran, Questran Light, Cholestyramine Light, Locholest Light, Locholest, Prevalite)
 - colestipol (Colestipol hydrochloride, Colestid, Flavored Colestid)
- medicines used to treat diabetes, including insulin.
- lithium, a medicine used to treat some types of depression. You should not take Amturnide 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.
- sleeping pills and anti-seizure medicines called barbiturates
- narcotic pain 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 Amturnide?

- Take Amturnide exactly as prescribed by your doctor. It is important to take Amturnide every day to control your blood pressure.
- Take Amturnide one time a day, at about the same time each day.
- Take Amturnide the same way every day, either with or without a meal.
- Your doctor may change your dose of Amturnide if needed. Do not change the amount of Amturnide you take without talking to your doctor.
- If you miss a dose of Amturnide, 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 Amturnide, call your doctor or a Poison Control Center, or go to the nearest hospital emergency room.

What should I avoid while taking Amturnide?

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

What are the possible side effects of Amturnide?

Amturnide may cause serious side effects, including:

- **Harm to an unborn baby causing injury or death.** See “What is the most important information I should know about Amturnide?”
- **Angioedema.** Aliskiren, one of the medicines in Amturnide, can cause swelling of your 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. Serious allergic reactions can happen at any time while you are taking Amturnide.
- **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.
- **Worsening chest pain or heart attack.** When you first start taking Amturnide or increase your dose, you may have a heart attack or your angina may get worse. If that happens, call your doctor right away or go directly to the nearest hospital emergency room.
- **Allergic reactions.** Hydrochlorothiazide, one of the medicines in Amturnide, can cause allergic reactions.
- **Worsening of lupus.** One of the medicines in Amturnide may cause your lupus to become active or get worse. Tell your doctor if your lupus gets worse or becomes active while taking Amturnide.
- **Low potassium level (hypokalemia).** Your doctor will do blood tests to check your potassium levels.
- **Eye problems.** One of the medicines in Amturnide can cause eye problems that may lead to vision loss. Symptoms of eye problems can happen within hours to weeks of starting Amturnide. Tell your doctor right away if you have:
 - decrease in vision
 - eye pain

The most common side effects of Amturnide include:

- swelling of your ankles, feet, and hands
- dizziness
- headache
- stuffy or runny nose and sore throat

Common side effects of Amturnide include:

- diarrhea
- cough
- tiredness
- high levels of potassium in the blood (hyperkalemia)

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 Amturnide. For more information 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 should I store Amturnide?

- Store Amturnide tablets at room temperature between 59°F to 86°F (15°C to 30°C).
- Keep Amturnide in the original container.
- Protect Amturnide from heat and moisture.

Keep Amturnide and all medicines out of the reach of children.

General information about Amturnide

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

For more information about Amturnide, visit www.Amturnide.com, or call 1-888-NOW-NOVA (1-888-669-6682).

What are the ingredients in Amturnide?

Active ingredients: Aliskiren hemifumarate, amlodipine besylate, and HCTZ.

Inactive ingredients: colloidal silicon dioxide, crospovidone, hypromellose, iron oxide red, iron oxide yellow, iron oxide black, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, talc, and titanium dioxide.

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 through the body and causes damage to blood vessels. Amturnide 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.

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