

FDA-Approved Patient Labeling

Patient Information Tekamlo™ (*těk'-ăm-lō*) Tekamlo (aliskiren and amlodipine) Tablets

Read the Patient Information that comes with Tekamlo before you start taking it and each time you get a refill. There may be new information. This information does not take the place of talking with your doctor about your condition and treatment. If you have any questions about Tekamlo, ask your doctor or pharmacist.

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

Tekamlo 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 Tekamlo, tell your doctor right away.

What is Tekamlo?

Tekamlo is a prescription medicine that may be used:

- as the first medicine to lower your high blood pressure if your doctor decides that you are likely to need more than one medicine.
- to treat your high blood pressure when one medicine to lower your high blood pressure has not worked well enough.
- if you are already taking the medicines aliskiren and amlodipine to treat your high blood pressure.

Tekamlo contains:

- aliskiren, a direct renin inhibitor (DRI)
- amlodipine, a calcium channel blocker (CCB)

Your doctor may prescribe other medicines for you to take along with Tekamlo to treat your high blood pressure.

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

Who should not take Tekamlo?

- If you get pregnant, stop taking Tekamlo 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.
- **If you are allergic** (hypersensitive) to aliskiren, amlodipine or other dihydropyridines (calcium-channel blockers, a group of medicines to lower blood pressure to which amlodipine belongs) or any of the other ingredients of Tekamlo listed at the end of this leaflet.

What should I tell my doctor before taking Tekamlo?

Before taking Tekamlo, tell your doctor if you:

- have kidney problems
- have liver problems

- have ever 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 Tekamlo?”**
- are breastfeeding. It is not known if Tekamlo passes into your breast milk and if it can harm your baby. You and your doctor should decide if you will take Tekamlo 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. Tekamlo and certain other medicines may affect each other and cause side effects.

Especially tell your doctor if you take:

- 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
- atorvastatin (Lipitor[®]) non-steroidal anti-inflammatory drugs (like ibuprofen or naproxen)

Know your medicines. Keep a list of all your medicines. Show this list to 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 Tekamlo?

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

What are the possible side effects of Tekamlo?

Tekamlo 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 Tekamlo?”**
- Aliskiren, one of the medicines in Tekamlo, 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 Tekamlo.

- **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. Lie down if you feel faint or get dizzy. Call your doctor right away.
- **Possible increased chest pain or risk of heart attack.** It is rare, but when you first start taking Tekamlo 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 a hospital emergency room.

The most common side effects of Tekamlo include:

- Swelling of your lower legs

Common side effects of Tekamlo include:

- diarrhea
- cough
- dizziness
- flu-like symptoms
- 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 Tekamlo. 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 do I store Tekamlo?

- Store Tekamlo tablets at room temperature between 59°F to 86°F (15°C to 30°C).
- Keep the original prescription bottle and store in a dry place.
- Protect Tekamlo from heat and moisture.

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

General information about Tekamlo

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

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

What are the ingredients in Tekamlo?

Active Ingredients: Aliskiren hemifumarate and amlodipine

Inactive ingredients: Colloidal silicon dioxide, crospovidone, hypromellose, iron oxide red, iron oxide yellow, 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. Tekamlo 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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