
Patient Information

Telmisartan and Amlodipine (TEL me SAR tan and am LOE de peen) Tablets

Read this Patient Information before you start taking telmisartan and amlodipine tablets and each time you get a refill. There may be new information. This information does not take the place of talking to your doctor about your medical condition or your treatment.

What is the most important information I should know about telmisartan and amlodipine tablets?

Telmisartan and amlodipine tablets 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 telmisartan and amlodipine tablets, tell your doctor right away.

What are telmisartan and amlodipine tablets?

Telmisartan and amlodipine tablets are a prescription medicine that contains telmisartan and amlodipine.

Telmisartan and amlodipine tablets may be used to treat high blood pressure (hypertension):

- when one of these medicines (or a similar one) is not enough to lower your high blood pressure
- as the first medicine to lower your high blood pressure if your doctor decides you are likely to need more than one medicine

It is not known if telmisartan and amlodipine tablets are safe and effective in children.

Who should not take telmisartan and amlodipine tablets?

You should not take telmisartan and amlodipine tablets if you are allergic (hypersensitive) to the active ingredients (telmisartan or amlodipine) or any of the other ingredients listed at the end of this leaflet.

For patients with diabetes, if you are taking telmisartan and amlodipine tablets you should not take aliskiren.

What should I tell my doctor before taking telmisartan and amlodipine tablets?

Before you take telmisartan and amlodipine tablets, tell your doctor if you:

- are pregnant or are planning to become pregnant. See “**What is the most important information I should know about telmisartan and amlodipine tablets?**”
- are breast-feeding or plan to breast-feed. Telmisartan and amlodipine can pass into your breast milk and may harm your baby. You and your doctor should decide if you will take telmisartan and amlodipine tablets or breast-feed. You should not do both. Talk with your doctor about the best way to feed your baby if you take telmisartan and amlodipine tablets.
- have liver problems
- have kidney problems
- have heart problems
- have any other medical conditions

Tell your doctor about all the medicines you take, including prescription and nonprescription medicines, vitamins and herbal supplements.

For patients with diabetes, if you are taking telmisartan and amlodipine tablets you should not take aliskiren.

Telmisartan and amlodipine tablets may affect the way other medicines work, and other medicines may affect how telmisartan and amlodipine tablets work. Especially tell your doctor if you take:

- aliskiren
- digoxin (Lanoxin[®])
- lithium (Lithobid[®], lithium carbonate, lithium citrate)
- aspirin or other non-steroidal anti-inflammatory drugs (NSAIDs)
- other medicines that may be used to treat high blood pressure or a heart problem
- simvastatin (Zocor[®], Vytorin[®])
- water pills (diuretics)

Know the medicines you take. Keep a list of them and show it to your doctor or pharmacist when you get a new medicine.

How should I take telmisartan and amlodipine tablets?

- Take telmisartan and amlodipine tablets exactly as your doctor tells you to take it.
- Your doctor will tell you how much telmisartan and amlodipine tablets to take and when to take it. Your doctor may change your dose if needed.
- Take telmisartan and amlodipine tablets one time each day at the same time.
- Take telmisartan and amlodipine tablets with or without food.
- If you miss a dose, take it as soon as you remember. If it is close to your next dose, do not take the missed dose. Take the next dose at your regular time.
- If you take too much telmisartan and amlodipine tablets, call your doctor or go to the nearest hospital emergency room right away.

What are possible side effects of telmisartan and amlodipine tablets?

Telmisartan and amlodipine tablets may cause serious side effects, including:

- **Injury or death to your unborn baby.** See “**What is the most important information I should know about telmisartan and amlodipine tablets?**”
- **Low blood pressure (hypotension)** is most likely to happen if you also:
 - take water pills (diuretics)
 - are on a low-salt diet
 - get dialysis treatments
 - have heart problems
 - get sick with vomiting or diarrhea

If you feel faint or dizzy, lie down and call your doctor right away.

- **Kidney problems.** Kidney problems may get worse if you already have kidney disease. You

may have changes in your kidney test results, and you may need a lower dose of telmisartan and amlodipine tablets. Call your doctor if you get:

- swelling in your feet, ankles, or hands
- unexplained weight gain

Call your doctor right away if you get any of the symptoms listed above.

- **Heart problems or heart attack.** Heart problems may get worse in people that already have heart disease. This may happen when you start telmisartan and amlodipine tablets or when there is an increase in your dose of telmisartan and amlodipine tablets. Get emergency help if you get worse chest pain or chest pain that does not go away.
- **High potassium in the blood (hyperkalemia).** Your doctor may check your potassium levels as needed.
- **Muscle rigidity,** tremor and/or abnormal muscle movement.

Rare, serious allergic reactions may happen. Tell your doctor right away if you get any of these symptoms:

- swelling of face, tongue, throat
- difficulty breathing
- skin rash

The most common side effects of telmisartan and amlodipine tablets include:

- swelling in your hands, ankles, or feet
- feeling like your heart is pounding or racing
- flushing or sudden redness of the face and neck
- dizziness
- back pain
- feeling tired or sleepy
- abdominal pain, nausea, or diarrhea
- low blood pressure or a sudden drop in blood pressure with fainting

These are not all the possible side effects of telmisartan and amlodipine tablets. Tell your doctor if you have any side effect that bothers you or that does not go away.

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 telmisartan and amlodipine tablets?

- Store telmisartan and amlodipine tablets at 20° to 25° C (68° to 77° F); excursions permitted to 15° to 30° C (59° to 86° F) [See USP Controlled Room Temperature].
- Do not remove telmisartan and amlodipine tablets from blisters until right before you take them.
- Keep telmisartan and amlodipine tablets out of the light and away from moisture.

Keep telmisartan and amlodipine tablets and all medicines out of the reach of children.

General information about telmisartan and amlodipine tablets

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use telmisartan and amlodipine tablets for a condition for which it was not prescribed. Do not give telmisartan and amlodipine tablets to other people, even if they have the same symptoms that you have. It may harm them.

This Patient Information leaflet summarizes the most important information about telmisartan and amlodipine tablets. If you would like more information, talk with your doctor. You can ask your pharmacist or doctor for information about telmisartan and amlodipine tablets that is written for health professionals. For more information, call Torrent Pharma Inc. at 1-800-912-9561.

What are the ingredients in telmisartan and amlodipine tablets?

Active ingredients: telmisartan, USP and amlodipine besylate, USP

Inactive ingredients: ferric oxide black, lake of brilliant blue, magnesium stearate, mannitol, meglumine, povidone, sodium hydroxide pellets and sodium stearyl fumarate.

What is high blood pressure (hypertension)?

Blood pressure is the force in your blood vessels when your heart beats and when your heart rests. You have high blood pressure when the force is too much. Telmisartan and amlodipine tablets can help your blood vessels relax so your blood pressure is lower. Medicines that lower your blood pressure lower your chance of having a stroke or heart attack.

High blood pressure makes the heart work harder to pump blood throughout the body and causes damage to the blood vessels. If high blood pressure is not treated, it can lead to stroke, heart attack, heart failure, kidney failure, and vision problems.

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This Patient Information has been approved by the U.S. Food and Drug Administration.



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April 2019