

Telmisartan (TEL-mi-SAR-tan) Tablets, USP

Read this Patient Information before you start taking telmisartan 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 tablets?

Telmisartan 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, tell your doctor right away.

What is telmisartan?

Telmisartan is a prescription medicine used:

- to treat high blood pressure (hypertension)
- in certain high risk people aged 55 years and older to help lower their risk of having certain cardiovascular problems such as stroke, heart attack, or death

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

Who should not take telmisartan tablets?

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

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

What should I tell my doctor before taking telmisartan tablets?

Before you take telmisartan 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 tablets?”**
- are breast-feeding or plan to breast-feed. It is not known if telmisartan passes into your breast milk. You and your doctor should decide if you will take telmisartan 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 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 non-prescription medicines, vitamins, and herbal supplements.

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

Telmisartan may affect the way other medicines work, and other medicines may affect how telmisartan works. 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 used to treat your high blood pressure or heart problem
- water pills (diuretic)

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 tablets?

- Take telmisartan tablets exactly as your doctor tells you to take it.
- Your doctor will tell you how much telmisartan to take and when to take it.
- Do not change your dose unless your doctor tells you to.
- Take telmisartan one time each day at the same time.

- Take telmisartan 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, call your doctor, or go to the nearest hospital emergency room right away.

What are the possible side effects of telmisartan tablets?

Telmisartan 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 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**, which 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 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.

- **High potassium in the blood (hyperkalemia).** Your doctor may check your potassium levels as needed.

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

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

The most common side effects of telmisartan tablets include:

- sinus pain and congestion (sinusitis)
- back pain
- diarrhea

These are not all the possible side effects with telmisartan 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 tablets?

- Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F).
- Do not remove telmisartan tablets from bottles until right before you take them.
- Bottle of 30's count comes in a child-resistant package.

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

General information about telmisartan tablets

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

This Patient Information leaflet summarizes the most important information about telmisartan tablets. If you would like more information, talk with your doctor. You can ask your pharmacist or doctor for information about telmisartan tablets that is written for health professionals.

For more information call 1-866-210-9797.

What are the ingredients in telmisartan tablets?

Active Ingredient: telmisartan

Inactive Ingredients: mannitol, sodium hydroxide, meglumine, povidone, sodium stearyl fumarate and magnesium stearate

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 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.

What is Cardiovascular Risk?

Patients older than 55 years of age who have been diagnosed with blood vessel disease in the heart, legs, or brain (coronary, peripheral, or cerebral vascular disease) or diabetes with end organ damage (for example: kidney, heart, and brain) are at higher risk of cardiovascular events (for example: death from cardiovascular causes, stroke, and/or heart attack).

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

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Revised: 05/2026