Package leaflet: Information for the user

Telmisartan Glenmark 20 mg, Film-coated Tablets
Telmisartan Glenmark 40 mg, Film-coated Tablets
Telmisartan Glenmark 80 mg, Film-coated Tablets

telmisartan

Read the entire leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you personally. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- Do you experience a lot of side effects listed in section 4? Or do you experience a side effect not listed in this leaflet? Then contact your doctor or pharmacist.

What is in this leaflet:

1. What Telmisartan Glenmark is and what it is used for

Telmisartan Glenmark belongs to a class of medicines known as angiotensin II receptor blockers. Angiotensin II is a substance produced in your body that narrows blood vessels, increasing blood pressure. Telmisartan Glenmark blocks this effect of angiotensin II, allowing blood vessels to widen and lowering blood pressure.

Telmisartan Glenmark is used for the treatment of essential high blood pressure (hypertension) in adults. 'Essential' means that the high blood pressure is not caused by another condition.

High blood pressure, if not treated, can damage blood vessels in various organs, which can sometimes lead to heart attacks, heart or kidney failure, strokes, or blindness. Usually, there are no symptoms of high blood pressure before such damage occurs. Therefore, it is necessary to measure whether the blood pressure is still within normal values.

Telmisartan Glenmark is also used to reduce the number of cardiovascular events (e.g., a heart attack or stroke) in adults who are at increased risk because they have reduced or blocked blood supply to the heart or legs, have had a stroke, or are at increased risk of diabetes. Your doctor can tell you if you are at high risk for such conditions.

2. What you need to know before you take Telmisartan Glenmark

Do not take Telmisartan Glenmark

if you are allergic to telmisartan or any of the other ingredients of this medicine (listed in section 6).
if you are more than 3 months pregnant; it is also better to avoid the use of Telmisartan Glenmark at the beginning of pregnancy (see the section on pregnancy).
if you have a severe liver disorder such as bile stasis or bile duct obstruction (a problem with the drainage of bile from the liver and gallbladder), or another severe liver disorder.
You have diabetes or impaired kidney function and are being treated with a blood pressure-lowering medicine that contains aliskiren.

Tell your doctor or pharmacist if any of the above apply to you before you take Telmisartan Glenmark.

Warnings and precautions

Talk to your doctor before using this medicine if you suffer or have suffered from any of the following conditions or diseases:

Kidney disease or kidney transplant
Renal artery stenosis (narrowing of the blood vessels to one or both kidneys)
Liver disease
Heart problems
Increased aldosterone levels (retention of water and salt in the body along with a disturbed balance of various minerals in the blood)
Low blood pressure (hypotension), this can occur if you are dehydrated (excessive loss of body fluid) or have a salt deficiency due to, for example, diuretic therapy ('water pills'), a low-salt diet, diarrhea, or vomiting
Increased potassium levels in your blood
Diabetes

Tell your doctor before you take Telmisartan Glenmark:

if you are taking any of the following medicines for the treatment of high blood pressure:
- an ACE inhibitor (for example enalapril, lisinopril, ramipril), especially if you have diabetes-related kidney problems
- aliskiren.

Your doctor may check your kidney function, blood pressure, and the number of electrolytes (e.g., potassium) in your blood. See also the information in the section “When should you not use this medicine?”

if you are using digoxin.

Tell your doctor if you think you are pregnant (or if you plan to become pregnant). The use of Telmisartan Glenmark is not recommended during the early stages of pregnancy and should not be used if you are more than 3 months pregnant, as it may cause serious adverse effects to your baby if used from that period (see the section on pregnancy).

During surgery or anesthesia, you must inform your doctor that you are using Telmisartan Glenmark.

Telmisartan Glenmark may be less effective in lowering blood pressure in patients of African descent.

Contact your doctor if you experience abdominal pain, nausea, vomiting, or diarrhea after taking this medicine. Your doctor will decide on further treatment. Do not stop using this medicine without consulting your doctor first.

Children and adolescents

The use of Telmisartan Glenmark in children and individuals up to 18 years is not recommended.

Other medicines and Telmisartan Glenmark

Tell your doctor or pharmacist if you are using or have recently used or might use other medicines. Your doctor may need to adjust the dosage of these other medicines or take other precautions. In some cases, you will need to stop taking one of the medicines. This is especially true for the medicines described below that are used simultaneously with Telmisartan Glenmark:

Lithium-containing medicines for the treatment of some forms of depression.
Medicines that can increase the potassium level in the blood, such as potassium-containing salt substitutes, potassium-sparing medicines, diuretics (certain 'water pills'), ACE inhibitors, angiotensin II receptor blockers, NSAIDs (non-steroidal anti-inflammatory drugs, e.g., aspirin or ibuprofen), heparin, immunosuppressants (e.g., cyclosporine or tacrolimus), and the antibiotic trimethoprim.
The use of diuretics ('water pills'), especially in high doses together with Telmisartan Glenmark, can lead to excessive loss of body fluid and low blood pressure (hypotension).
If you are taking an ACE inhibitor or aliskiren (see also the information in the sections "When should you not use this medicine?" and "When should you be extra careful with this medicine?").
A medication for the treatment of heart failure (digoxin).

The effect of Telmisartan Glenmark may decrease when you use NSAIDs (non-steroidal anti-inflammatory drugs, e.g., aspirin or ibuprofen) or corticosteroids.

Telmisartan Glenmark can enhance the blood pressure-lowering effect of other medications used for the treatment of high blood pressure or of medications with blood pressure-lowering potential (e.g., baclofen, amifostine). Additionally, low blood pressure may be worsened by alcohol, sleeping pills, drugs, or antidepressants. You may notice this as dizziness upon standing. Consult your doctor if the dose of your other medications needs to be adjusted while using Telmisartan Glenmark.

Pregnancy and breastfeeding

Pregnancy
Tell your doctor if you think you are pregnant or if you are planning to become pregnant. Normally, your doctor will advise you to stop taking Telmisartan Glenmark before you become pregnant or as soon as you know you are pregnant and will advise you to use another

medication instead of Telmisartan Glenmark. Telmisartan Glenmark is not recommended for use during early pregnancy and should not be used after the third month of pregnancy, as it may cause serious adverse effects to your baby if used after the third month.

Breastfeeding
Tell your doctor if you are breastfeeding or about to start breastfeeding. Telmisartan Glenmark is not recommended for mothers who are breastfeeding, and your doctor may choose another treatment if you wish to breastfeed, especially if your baby is newborn or premature.

Driving and using machines
Some people taking Telmisartan Glenmark may experience side effects such as fainting or a spinning sensation (vertigo). If you experience these side effects, you should not drive or operate machinery.
Telmisartan Glenmark contains lactose
If you are intolerant to certain sugars, consult your doctor before taking Telmisartan Glenmark.

Telmisartan Glenmark contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per tablet, meaning it is essentially 'sodium-free'.

3. How to take Telmisartan Glenmark

Always take Telmisartan Glenmark as prescribed by your doctor. Contact your doctor or pharmacist if you are unsure.

The recommended dose of Telmisartan Glenmark is one tablet per day. Try to take the tablet at the same time each day. You can take Telmisartan Glenmark with or without food. The tablet should be swallowed whole with some water or another non-alcoholic drink. It is important to take Telmisartan Glenmark every day until your doctor advises otherwise. If you feel that the effect of Telmisartan Glenmark is too strong or too weak, inform your doctor or pharmacist.

For the treatment of high blood pressure, the usual dose of Telmisartan Glenmark for most patients is one 40 mg tablet once daily to control blood pressure for 24 hours. However, your doctor may sometimes recommend a lower dose of 20 mg or a higher dose of 80 mg. Alternatively, Telmisartan Glenmark can be used in combination with diuretics ('water pills'), such as hydrochlorothiazide, which has been shown to have an additional blood pressure-lowering effect with Telmisartan Glenmark.

To reduce cardiovascular events, the usual dose of Telmisartan Glenmark is one 80 mg tablet once daily. At the start of preventive treatment with Telmisartan Glenmark 80 mg, blood pressure should be regularly monitored.

If your liver is not functioning properly, the daily dose of 40 mg should not be exceeded.

Have you taken too much of this medicine?

If you accidentally take too many tablets, contact your doctor, pharmacist, or the emergency department of the nearest hospital immediately.

Have you forgotten to take this medicine?

Do not worry if you have missed a dose. Take it as soon as you remember and continue as before. If you have missed your tablet for one day, take the normal next dose the following day. Do not take a double dose to make up for a forgotten dose.

If you stop taking Telmisartan Glenmark

Do not stop taking Telmisartan Glenmark without consulting your doctor.
Medicines for high blood pressure are sometimes taken for life. If you stop taking this medicine, your blood pressure will increase again to the level before treatment within a few days.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Some side effects can be serious and require immediate medical attention:

You should contact your doctor immediately if you experience any of the following symptoms:

Sepsis* (often called 'blood poisoning', is a severe infection with an inflammatory response throughout the body that can lead to death), rapid swelling of the skin and mucous membranes (angioedema); these side effects are rare but particularly serious and patients should stop using this medicine and consult a doctor immediately. If these symptoms are not treated, they can be fatal.

Possible side effects of Telmisartan Glenmark:

Common side effects (occur in less than 1 in 10 people):
Low blood pressure (hypotension) in patients treated to reduce cardiovascular events.

Uncommon side effects (occur in less than 1 in 100 people): Urinary tract infection, upper respiratory tract infection (e.g., sore throat, sinusitis, cold), anemia, high potassium levels, difficulty sleeping, feeling sad (depression), fainting (syncope), spinning sensation (vertigo), slow heart rate (bradycardia), low blood pressure (hypotension) in users treated for high blood pressure, dizziness upon standing (orthostatic hypotension), shortness of breath, cough, abdominal pain, diarrhea, abdominal discomfort, bloating, vomiting, itching, increased sweating, drug-induced rash, back pain, muscle cramp, muscle pain (myalgia), impaired kidney function including acute kidney failure, chest pain, feeling of weakness, and increased blood creatinine levels.

Rare side effects (occur in less than 1 in 1,000 people):
Sepsis* (often called 'blood poisoning', is a severe infection with an inflammatory response throughout the body that can lead to death), increase in certain white blood cells

(eosinophilia), reduction in blood platelets (thrombocytopenia), severe allergic reaction (anaphylactic reaction), allergic reaction (e.g., skin rash, itching, breathing problems, wheezing, swelling of the face or low blood pressure), low blood glucose level (in diabetic patients), anxiety, drowsiness, impaired vision, rapid heartbeat (tachycardia), dry mouth, abdominal discomfort, taste disorder (dysgeusia), abnormal liver function (patients of Japanese descent are more likely to experience this side effect), rapid swelling of skin and mucous membranes which can also lead to death (angioedema, also with fatal outcome), eczema (a skin condition), red skin, hives (urticaria), severe drug-induced skin rash, joint pain (arthralgia), pain in arms and legs, painful tendon, flu-like illness, a reduced level of hemoglobin (a blood protein), increased levels of uric acid, an increased level of liver enzymes or creatine phosphokinase in the blood, low sodium level.

Very rare side effects (occur in less than 1 in 10,000 people): Progressive scarring of lung tissue (interstitial lung disease) **

Not known (frequency cannot be determined from the available data):
Intestinal angioedema: a swelling in the intestines with symptoms such as abdominal pain, nausea, vomiting, and diarrhea has been reported after using similar products.

* This may be coincidental or due to an as yet unknown mechanism.

** Most cases of abnormal liver function occurred in patients of Japanese descent. Patients of Japanese descent are more likely to experience this side effect.

If you experience one or more side effects, contact your doctor or pharmacist. This also applies to possible side effects not listed in this leaflet.

Reporting side effects
If you experience side effects, contact your doctor or pharmacist. This also applies to possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system as mentioned in the Netherlands Pharmacovigilance Centre Lareb Website: www.lareb.nl . By reporting side effects, you can help us obtain more information about the safety of this medicine.

5. How to store Telmisartan Glenmark

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the box after 'EXP'. The expiry date refers to the last day of that month.

There are no special storage conditions for this medicine.

Medicines should not be disposed of via wastewater or with household waste. Ask your pharmacist what to do with medicines you no longer need. These measures will help protect the environment.

6. Contents of the pack and other information

What does Telmisartan Glenmark contain
The active ingredient is telmisartan. Each tablet contains 20, 40, or 80 mg of telmisartan. The other substances in the core of this medicine are sodium hydroxide, povidone (K-25), meglumine, lactose monohydrate, crospovidone, iron oxide yellow (E172), magnesium stearate.

The other substances in the film coating of this medicine are hypromellose, titanium dioxide (E171), macrogol-400, talc, iron oxide yellow (E172).

What does Telmisartan Glenmark look like and what is in a package
Telmisartan 20 mg Glenmark, Film-coated Tablets are yellow and round with the marking '20' on one side and 'T' on the other side.

Telmisartan 40 mg Glenmark, Film-coated Tablets are yellow and capsule-shaped with the marking
'40' on one side and 'T' on the other side.

Telmisartan 80 mg Glenmark, Film-coated Tablets are yellow and capsule-shaped with the marking
'80' on one side and 'T' on the other side.

The tablets are available in blister packs (push-through strips) of 14, 15, 28, 30, 56, 60, 84, 90, or 98 tablets.
Not all mentioned pack sizes are marketed.

Marketing authorization holder and manufacturer:
Glenmark Arzneimittel GmbH,
Industriestr. 31,
82194 Gröbenzell,
Germany

Manufacturer:
Glenmark Pharmaceuticals sro.,
City Tower, Hvezdova 1716/2B,
Prague 4, CZ-140 78,
Czech Republic

Registered under
Telmisartan Glenmark 20 mg, film-coated tablets: RVG 106142
Telmisartan Glenmark 40 mg, film-coated tablets: RVG 106144
Telmisartan Glenmark 80 mg, film-coated tablets: RVG 106145

This medicine is registered in member states of the European Economic Area under the following names:

Germany Telmisartan Glenmark 20/40/80 mg Filmtabletten
Spain Telmisartán VIR 20/40/80 mg comprimidos recubiertos con película EFG Netherlands
Telmisartan Glenmark 20/40/80 mg, film-coated tablets

This leaflet was last approved in May 2025.