

Telmisartan 20 mg, 40 mg and 80 mg Tablets

PACKAGE LEAFLET: INFORMATION FOR THE USER

Read all of this 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 further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Telmisartan Tablets are and what they are used for
2. What you need to know before you take Telmisartan Tablets
3. How to take Telmisartan Tablets
4. Possible side effects
5. How to store Telmisartan Tablets
6. Contents of the pack and other information

1 What Telmisartan Tablets are and what they are used for

Telmisartan Tablets contains the active substance telmisartan. This belongs to a class of medicines known as angiotensin II receptor antagonists. Angiotensin II is a substance produced in your body which causes your blood vessels to narrow, thus increasing your blood pressure. Telmisartan blocks the effect of angiotensin II so that the blood vessels relax, and your blood pressure is lowered.

Telmisartan tablets are used

to treat essential hypertension (high blood pressure) in adults. 'Essential' means that the high blood pressure is not caused by any other condition.

High blood pressure, if not treated, can damage blood vessels in several organs, which could lead sometimes to heart attack, heart or kidney failure, stroke, or blindness. There are usually no symptoms of high blood pressure before damage occurs. Thus it is important to regularly measure blood pressure to verify if it is within the normal range.

Telmisartan tablets are also used

to reduce cardiovascular events (i.e. heart attack or stroke) in adults who are at risk because they have a reduced or blocked blood supply to the heart or legs, or have had a stroke or have high risk diabetes. Your doctor can tell you if you are at high risk for such events.

You must talk to a doctor if you do not feel better or if you feel worse.

2 What you need to know before you take Telmisartan Tablets

Do not take Telmisartan Tablets

- if you are allergic to telmisartan or any other ingredients of this medicine (listed in section 6)
- if you are more than 3 months pregnant. (It is also better to avoid Telmisartan Tablets in early pregnancy – see pregnancy section)
- if you have severe liver problems such as cholestasis or biliary obstruction (problems with the drainage of the bile from the liver and gall bladder) or any other severe liver disease
- if you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren

If any of the above applies to you, tell your doctor or pharmacist before taking Telmisartan Tablets.

Warnings and precautions

Talk to your doctor before taking Telmisartan Tablets if you are suffering or have ever suffered from any of the following conditions or illnesses:

- Kidney disease or kidney transplant
- Renal artery stenosis (narrowing of the blood vessels to one or both kidneys)
- Liver disease
- Heart trouble
- Raised aldosterone levels (water and salt retention in the body along with imbalance of various blood minerals)
- Low blood pressure (hypotension), likely to occur if you are dehydrated (excessive loss of body water) or have salt deficiency due to diuretic therapy ('water tablets'), low-salt diet, diarrhoea, or vomiting
- Elevated potassium levels in your blood
- Diabetes

Talk to your doctor before taking Telmisartan Tablets:

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

Your doctor may check your kidney function, blood pressure, and the amount of electrolytes (e.g. potassium) in your blood at regular intervals. See also information under the heading "Do not take Telmisartan Tablets"

- if you are taking digoxin.

- Talk to your doctor if you experience abdominal pain, nausea, vomiting or diarrhoea after taking Telmisartan Tablets. Your doctor will decide on further treatment. Do not stop taking Telmisartan Tablets on your own.

You must tell your doctor if you think you are (or might become) pregnant. Telmisartan Tablets is not recommended in early pregnancy, and must not be taken if you are more than 3 months pregnant, as it may cause serious harm to your baby if used at that stage (see pregnancy section).

In case of surgery or anaesthesia, you should tell your doctor that you are taking Telmisartan Tablets.

Telmisartan Tablets may be less effective in lowering the blood pressure in black patients.

Children and adolescents

The use of Telmisartan Tablets in children and adolescents up to the age of 18 years is not recommended.

Other medicines and Telmisartan Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Your doctor may need to change the dose of these other medicines or take other precautions. In some cases you may have to stop taking one of the medicines. This applies especially to the medicines listed below taken at the same time with Telmisartan Tablets:

- Lithium containing medicines to treat some types of depression
- Medicines that may increase blood potassium levels such as salt substitutes containing potassium, potassium-sparing diuretics (certain 'water tablets'), ACE inhibitors, angiotensin II receptor antagonists, NSAIDs (non steroidal anti-inflammatory medicines, e.g. aspirin or ibuprofen), heparin, immunosuppressives (e.g. cyclosporin or tacrolimus), and the antibiotic trimethoprim
- Diuretics ('water tablets'), especially if taken in high doses together with Telmisartan Tablets, may lead to excessive loss of body water and low blood pressure (hypotension)
- If you are taking an ACE-inhibitor or aliskiren (see also information under the headings "Do not take Telmisartan Tablets" and "Warnings and precautions").
- Digoxin

The effect of Telmisartan Tablets may be reduced when you take NSAIDs (non steroidal anti-inflammatory medicines, e.g. aspirin or ibuprofen) or corticosteroids.

Telmisartan Tablets may increase the blood pressure lowering effect of other medicines used to treat high blood pressure or of medicines with blood pressure lowering potential (e.g. baclofen, amifostine).

Furthermore, low blood pressure may be aggravated by alcohol, barbiturates, narcotics or antidepressants. You may notice this as dizziness when standing up. You should consult with your doctor if you need to adjust the dose of your other medicine while taking Telmisartan Tablets.

Pregnancy and breast-feeding

Pregnancy

You must tell your doctor if you think you are (or might become) pregnant. Your doctor will normally advise you to stop taking Telmisartan Tablets before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Telmisartan Tablets. Telmisartan Tablets is not recommended in early pregnancy, and must not be taken when more than 3 months pregnant, as it may cause serious harm to your baby if used after the third month of pregnancy.

Breast-feeding

Tell your doctor if you are breast-feeding or about to start breast-feeding. Telmisartan Tablets is not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breast-feed, especially if your baby is newborn, or was born prematurely.

Driving and using machines

Some people feel dizzy or tired when they are taking Telmisartan Tablets. If you feel dizzy or tired, do not drive or operate machinery.

Telmisartan Tablets contain sorbitol.

Telmisartan Tablets 20 mg

This medicine contains 9.6 mg sorbitol in each tablet.

Telmisartan Tablets 40 mg

This medicine contains 19.2 mg sorbitol in each tablet.

Telmisartan Tablets 80 mg

This medicine contains 38.4 mg sorbitol in each tablet.

Telmisartan Tablets contain sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3 How to take Telmisartan Tablets

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is one tablet a day. Try to take the tablet at the same time each day.

You can take Telmisartan Tablets with or without food. The tablets should be swallowed with some water or other non-alcoholic drink. It is important that you take Telmisartan Tablets every day until your doctor tells

you otherwise. If you have the impression that the effect of Telmisartan Tablets is too strong or too weak, talk to your doctor or pharmacist.

For treatment of high blood pressure:

The usual dose of Telmisartan Tablets for most patients is one 40 mg tablet once a day to control blood pressure over the 24-hour period. However, sometimes your doctor may recommend a lower dose of 20 mg or a higher dose of 80 mg. Alternatively, Telmisartan Tablets may be used in combination with diuretics ('water tablets') such as hydrochlorothiazide which has been shown to have an additive blood pressure lowering effect with Telmisartan Tablets.

For reduction of cardiovascular events:

The usual dose of Telmisartan Tablets is one 80 mg tablet once a day. At the beginning of the preventive therapy with Telmisartan Tablets, blood pressure should be frequently monitored.

If your liver is not working properly, the usual dose should not exceed 40 mg once daily.

If you take more Telmisartan Tablets than you should
If you accidentally take too many tablets, contact your doctor, pharmacist, or your nearest hospital emergency department immediately.

If you forget to take Telmisartan Tablets

If you forget to take a dose, do not worry. Take it as soon as you remember then carry on as before. If you do not take your tablet on one day, take your normal dose on the next day.

Do not take a double dose to make up for forgotten individual doses.

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 need immediate medical attention:

You should see your doctor immediately if you experience any of the following symptoms:
Sepsis* (often called "blood poisoning", is a severe infection with whole-body inflammatory response, which can lead to death), rapid swelling of the skin and mucosa which can also lead to death (angioedema also with fatal outcome). Severe allergic reaction (anaphylactic reaction), allergic reaction (e.g. rash, itching, difficulty breathing, wheezing, swelling of the face or low blood pressure). These side effects are rare (may affect up to 1 in 1,000 people) but are extremely serious and patients should stop taking the medicine and see their doctor immediately. If these effects are not treated they could be fatal.

Possible side effects of Telmisartan Tablets:

Common: may affect up to 1 in 10 people

low blood pressure (hypotension) in users treated for reduction of cardiovascular events.

Uncommon: may affect up to 1 in 100 people

- urinary tract infections
- upper respiratory tract infections (e.g. sore throat, inflamed sinuses, common cold)
- deficiency in red blood cells (anaemia)
- high potassium levels
- difficulty falling asleep
- feeling sad (depression)
- fainting (syncope)
- feeling of spinning (vertigo)
- slow heart rate (bradycardia)
- low blood pressure (hypotension) in users treated for high blood pressure
- dizziness on standing up (orthostatic hypotension)
- shortness of breath
- cough
- abdominal pain
- diarrhoea
- discomfort in the abdomen
- bloating
- being sick
- itching
- increased sweating
- drug rash
- back pain
- muscle cramps
- muscle pain (myalgia)
- kidney impairment including acute kidney failure
- pain in the chest
- feeling of weakness
- increased level of creatinine in the blood.

Rare: may affect up to 1 in 1,000 people

- increase in certain white blood cells (eosinophilia)
- low platelet count (thrombocytopenia)
- low blood sugar levels (in diabetic patients)
- feeling anxious
- somnolence
- impaired vision
- fast heart beat (tachycardia)
- dry mouth
- upset stomach
- taste disturbance (dysgeusia)
- abnormal liver function (Japanese patients are more likely to experience this side effect)
- eczema (a skin disorder)
- redness of skin

- hives (urticaria)
- severe drug rash
- joint pain (arthralgia)
- pain in extremity
- tendon pain
- flu-like-illness
- decreased haemoglobin (a blood protein)
- increased levels of uric acid
- increased hepatic enzymes or creatine phosphokinase in the blood.

Very rare: may affect up to 1 in 10,000 people

- progressive scarring of lung tissue (interstitial lung disease)**.

Frequency 'not known' (frequency cannot be estimated from the available data)

- Intestinal angioedema: a swelling in the gut presenting with symptoms like abdominal pain, nausea, vomiting, and diarrhoea has been reported after the use of similar products.

*The event may have happened by chance or could be related to a mechanism currently not known.

**Cases of progressive scarring of lung tissue have been reported during intake of telmisartan. However, it is not known whether telmisartan was the cause.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Telmisartan Tablets

Keep this medicine out of the sight and reach of children.

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

Bottle

Shelf life after 1st opening: 6 months.

This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6 Contents of the pack and other information

What Telmisartan Tablets contain:

The active substance is telmisartan.
Each 20 mg tablet contains 20 mg telmisartan.
Each 40 mg tablet contains 40 mg telmisartan.
Each 80 mg tablet contains 80 mg telmisartan.

The other ingredients are:

Mannitol, meglumine, sorbitol (E420), povidone (K-90), sodium hydroxide, hypromellose, magnesium stearate

What Telmisartan Tablets look like and contents of the pack

20 mg Tablets:

White to off white, round, flat bevelled tablets plain on both sides.

Telmisartan 20 mg Tablets is available in packs of 10, 14, 20, 28, 30, 56, 60, 84, 90, 98, 100 tablets.

40 mg Tablets:

White to off white, oblong tablets with a break line on one side.

The tablet can be divided into equal halves.

Telmisartan 40 mg Tablets are available in packs of 7, 10, 14, 20, 28, 30, 50, 56, 60, 84, 90, 98, 100 tablets.

80 mg Tablets:

White to off white, oblong tablets with a break line on one side.

The tablet can be divided into equal halves.

Telmisartan 80 mg Tablets are available in packs of 7, 10, 14, 20, 28, 30, 50, 56, 60, 84, 90, 98, 100 tablets and multipacks containing 98 (2 packs of 49) tablets.

Bottle (HDPE) with white cap (PP)

Pack sizes:

100 tablets
500 tablets (only for hospital use)
(Not all pack sizes may be marketed).

Marketing Authorisation Holder

Teva UK Limited, Ridings Point, Whistler Drive, Castleford, WF10 5HX, United Kingdom

Manufacturer:

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BLB015- BLB016 Bulebel Industrial Estate
Zejtun , ZTN3000, Malta

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