Package leaflet: Information for the patient

Telmisartan HEXAL® 20 mg, tabletten
Telmisartan HEXAL® 40 mg, tabletten
Telmisartan HEXAL® 80 mg, tabletten

telmisartan

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 [nationally completed name] is and what it is used for

[Nationally completed name] 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. [Nationally completed name] blocks the effect of angiotensin II so that the blood vessels relax, and your blood pressure is lowered.

[Nationally completed name] **is 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.

[Nationally completed name] is 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.

2. What you need to know before you take [nationally completed name]

Do NOT take [nationally completed name]:
- 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 [Nationally completed name] in early pregnancy – see pregnancy section.)
- if you have **severe liver problems** such as cholestasis or biliary obstruction (problems with the drainage of 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 [nationally completed name].

Warnings and precautions
Talk to your doctor 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 problems
- 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'), a low-salt diet, diarrhoea, or vomiting
- elevated potassium levels in your blood
- diabetes.

Talk to your doctor before taking [nationally completed name]:
- 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
- if you are taking digoxin.

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 [Nationally completed name]”.

You must tell your doctor if you think you are (or might become) **pregnant**. [Nationally completed name] 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**, tell your doctor that you are taking [nationally completed name].

[Nationally completed name] may be less effective in lowering blood pressure in **black patients**.

Children and adolescents
The use of [nationally completed name] in **children** and adolescents up to the age of 18 years is not recommended.

Other medicines and [nationally completed name]
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 [nationally completed name]:

- 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. acetylsalicylic acidc or ibuprofen), heparin, immunosuppressives (e.g. cyclosporin or tacrolimus), and the antibiotic trimethoprim
- diuretics ('water tablets'), especially if taken in high doses together with [nationally completed name], may lead to excessive loss of body water and low blood pressure (hypotension)
- an ACE-inhibitor or aliskiren (see also information under the headings “Do not take [nationally completed name]” and “Warnings and precautions”)
- digoxin.

The effect of [nationally completed name] may be reduced when you take NSAIDs (non steroidal anti-inflammatory medicines, e.g. acetylsalicylic acid or ibuprofen) or corticosteroids.

[Nationally completed name] 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 [nationally completed name].

[Nationally completed name] with food and drink
You can take [nationally completed name] with or without food.

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 [nationally completed name] before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of [nationally completed name]. [Nationally completed name] 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. [Nationally completed name] 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 taking [nationally completed name]. If you feel dizzy or tired, do not drive or operate machinery.

[Nationally completed name] contains lactose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

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

3. How to take [nationally completed name]

Always take [nationally completed name] exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose of [nationally completed name] is one tablet a day.
- Try to take the tablet at the same time each day.
- You can take [nationally completed name] with or without food.
- The tablets should be swallowed with some water or other non-alcoholic drink.
- It is important that you take [nationally completed name] every day until your doctor tells you otherwise.
- If you have the impression that the effect of [nationally completed name] is too strong or too weak, talk to your doctor or pharmacist.
- Tablets with a score line can be divided into equal halves

For treatment of high blood pressure, the usual dose of [nationally completed name] 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.

[Nationally completed name] may also be used in combination with diuretics ('water tablets') such as hydrochlorothiazide which has been shown to have an additive blood pressure lowering effect with [nationally completed name].

For reduction of cardiovascular events, the usual dose of [nationally completed name] is one 80 mg tablet once a day. At the beginning of the preventive therapy with [nationally completed name] 80 mg, blood pressure should be frequently monitored.

Use in children
The use of [nationally completed name] in **children** and adolescents up to the age of 18 years is not recommended.

Use in impaired liver function
If your liver is not working properly, the usual dose should not be more than 40 mg once daily.

Use in impaired kidney function
No dosage adjustment is necessary in patients with impaired kidney function.
If you have severe kidney function impairment or if you are undergoing haemodialysis your doctor may prescribe a lower starting dose of 20 mg.

If you take more [nationally completed name] 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 [nationally completed name]
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 stop taking [nationally completed name]
Always consult your doctor if you wish to stop taking this medicine. Even if you feel well, it may be necessary to continue taking this medicine.

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), rapid swelling of the skin and mucosa (angioedema); 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:

Common side effects (may affect up to 1 in 10 people):
- low blood pressure (hypotension) in users treated for reduction of cardiovascular events

Uncommon side effects (may affect up to 1 in 100 people):
- urinary tract infections
- upper respiratory tract infection (e.g. sore throat, inflamed sinuses, common cold)
- deficiency in red blood cells (anaemia)
- high potassium levels
- difficulty falling asleep (insomnia)
- 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
- vomiting
- 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 side effects (may affect up to 1 in 1,000 people):
- sepsis* (often called “blood poisoning”, is a severe infection with whole-body inflammatory response which can lead to death)
- increase in certain white blood cells (eosinophilia)
- low platelet count (thrombocytopenia)

- severe allergic reaction (anaphylactic reaction)
- allergic reaction (e.g. rash, itching, difficulty breathing, wheezing, swelling of the face or low blood pressure).
- 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)
- rapid swelling of the skin and mucosa which can also lead to death (angioedema also with fatal outcome)
- 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 side effects (may affect up to 1 in 10,000 people):
- progressive scarring of lung tissue (interstitial lung disease)**.

* 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 national reporting system listed in Appendix V*. By reporting side affects you can help provide more information on the safety of this medicine.
[*For the printed material, please refer to the guidance of the annotated QRD template.]

5. How to store **[nationally completed name]**

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 and blister after EXP. The expiry date refers to the last day of that month.

Store in the original package in order to protect from moisture.

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 [nationally completed name] contains

- The active substance is telmisartan. Each tablet contains 20 mg of telmisartan.
- The active substance is telmisartan. Each tablet contains 40 mg of telmisartan.
- The active substance is telmisartan. Each tablet contains 80 mg of telmisartan.
- The other ingredients are sodium hydroxide, meglumine, povidone K25, lactose monohydrate, povidone, crospovidone, lactose anhydrous, magnesium stearate.

What [nationally completed name] looks like and contents of the pack

[Nationally completed name]
White, round, plane tablet, debossed with '20' on one side.
The tablets dimension is 6.9-7.2 mm.

[Nationally completed name]
White, oblong, plaen tablet, scored on one side and debossed with '40' on the other side.
The tablets are 11.5-11.8 mm long and 6.4-6.8 mm wide.

[Nationally completed name]
White, oblong, plane tablet, scored on one side and debossed with '80' on the other side.
The tablets are 14.7-15.0 mm long and 8.2-8.6 mm wide.

<NL/H/1801/001-003>
Alu//Alu blisters containing 7, 10, 14, 20, 21, 28, 30, 50, 56, 60, 84, 90, 98, 100 tablets.

Alu//Alu unit dose blisters containing 28 tablets.

<NL/H/1802/001-003, NL/H/1803/001-003>
Alu//Alu blisters containing 7, 10, 14, 20, 21, 28, 30, 50, 56, 60, 84, 90, 98, 100 tablets.

<NL/H/1804/001-003, NL/H/1815/001-003>
Alu//Alu blisters containing 28 tablets.

<NL/H/1821/001-003>
Alu//Alu blisters containing 14, 28, 56, 98 tablets.

Not all pack sizes may be marketed.

Houder van de vergunning voor het in de handel brengen en fabrikant

Houder van de vergunning voor het in de handel brengen
Hexal AG
Industriestrasse 25
83607 Holzkirchen
Duitsland

Fabrikanten
Lek Pharmaceuticals d.d.
Verovškova 57
1526 Ljubljana
Slovenië

Lek Pharmaceuticals d.d.
Trimlini 2D
9220 Lendava
Slovenië

LEK S.A.
ul. Domaniewska 50 C
02-672 Warschau
Polen

Salutas Pharma GmbH
Otto-von-Guericke Allee 1
39179 Barleben
Duitsland

S.C. Sandoz, S.R.L.
Str. Livezeni nr 7A, 540472,
Targu Mures
Roemenië

In het register ingeschreven onder:
Telmisartan HEXAL 20 mg is in het register ingeschreven onder RVG 105925
Telmisartan HEXAL 40 mg is in het register ingeschreven onder RVG 105926
Telmisartan HEXAL 80 mg is in het register ingeschreven onder RVG 105927.

Dit geneesmiddel is geregistreerd in lidstaten van de EEA onder de volgende namen:
Duitsland: Telmisartan HEXAL 20 mg Tabletten
Telmisartan HEXAL 40 mg Tabletten
Telmisartan HEXAL 80 mg Tabletten

Nederland:	Telmisartan HEXAL 20 mg, tabletten Telmisartan HEXAL 40 mg, tabletten Telmisartan HEXAL 80 mg, tabletten

Deze bijsluiter is voor het laatst goedgekeurd in april 2019.