Package leaflet: Information for the user

Telmisartan/hydrochloorthiazide Sandoz 40 mg/12,5 mg, omhulde tabletten
Telmisartan/hydrochloorthiazide Sandoz 80 mg/12,5 mg, omhulde tabletten
Telmisartan/hydrochloorthiazide Sandoz 80 mg/25 mg, omhulde tabletten

Telmisartan/hydrochlorothiazide

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] is a combination of two active substances, telmisartan and hydrochlorothiazide in one tablet. Both of these substances help to control high blood pressure.

- Telmisartan belongs to a group of medicines called 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.

- Hydrochlorothiazide belongs to a group of medicines called thiazide diuretics, which cause your urine output to increase, leading to a lowering of your blood pressure.

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 used to treat high blood pressure (essential hypertension) in adults whose blood pressure is not controlled enough when telmisartan is used alone.

[nationally completed name] is used to treat high blood pressure (essential hypertension) in adults whose blood pressure is not adequately controlled by [nationally completed name] 80/12.5 mg or in patients who have been previously stabilised by telmisartan and hydrochlorothiazide given separately.

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 other ingredients of this medicine (listed in section 6).
- if you are **allergic to hydrochlorothiazide** or to any other sulfonamide-derived medicines.
- 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 drainage of the bile from the liver and gall bladder) or any other severe liver disease.
- if you have **severe kidney disease**.
- if your doctor determines that you have **low potassium levels** or **high calcium levels in your blood** that do not get better with treatment.
- 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 before taking [nationally completed name] if you are suffering or have ever suffered from any of the following conditions or illnesses:

- **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, vomiting, or haemodialysis.
- **Kidney disease** or **kidney transplant**.
- **Renal artery stenosis** (narrowing of the blood vessels to one or both kidneys).
- **Liver disease.**
- **Heart trouble.**

- **Diabetes.**
- **Gout.**
- **Raised aldosterone levels** (water and salt retention in the body along with imbalance of various blood minerals).
- **Systemic lupus erythematosus** (also called **"lupus"** or **"SLE"**) a disease where the body's immune system attacks the body.
- The active substance hydrochlorothiazide can cause an unusual reaction, resulting in a **decrease in vision** and **eye pain**. These could be symptoms of an increase of pressure in your eye and can happen within hours to weeks of taking Telmisartan /hydrochlorothiazide. This can lead to permanent vision impairment, if not treated.
- If you have had **skin cancer** or if you develop an unexpected **skin lesion** during the treatment. Treatment with hydrochlorothiazide, particularly long term use with high doses, may increase the risk of some types of skin and lip cancer (non-melanoma skin cancer). Protect your skin from sun exposure and UV rays while taking [nationally completed name].

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**

  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]".

- if you are taking **digoxin**, a medicine to treat heart diseases.

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).

Treatment with hydrochlorothiazide may cause electrolyte imbalance in your body. Typical symptoms of fluid or electrolyte imbalance include dry mouth, weakness, lethargy, drowsiness, restlessness, muscle pain or cramps, nausea (feeling sick), vomiting, tired muscles, and an abnormally fast heart rate (faster than 100 beats per minute). If you experience any of these you should tell your doctor.

You should also tell your doctor, if you experience an increased sensitivity of the skin to the sun with symptoms of sunburn (such as redness, itching, swelling, blistering) occurring more quickly than normal.

In case of surgery or anaesthetics, you should tell your doctor that you are taking [nationally completed name].

[nationally completed name] may be less effective in lowering the 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 medicinal 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 associated with low blood potassium (hypokalaemia) such as other diuretics (‘**water tablets’**), **laxatives** (e.g. castor oil), **corticosteroids** (e.g. prednisone), **ACTH** (a hormone), **amphotericin** (an antifungal medicine), **carbenoxolone** (used to treat mouth ulcers), **penicillin G sodium** (an antibiotic), and **salicylic acid** and derivatives.
- Medicines that may increase blood potassium levels such as **potassium-sparing diuretics, potassium supplements, salt substitutes containing potassium, ACE-inhibitors, cyclosporin** (an immunosuppressant medicine) and other medicines such as **heparin** sodium (an anticoagulant).
- **Heart medicines** (e.g. digoxin) or medicines to control the **rhythm of your heart** (e.g. quinidine, disopyramide, amiodarone, sotalol).
- Medicines used for **mental disorders** (e.g. thioridazine, chlorpromazine, levomepromazine).
- Certain **antibiotics** (e.g. sparfloxacine, pentamidine) or certain medicines to **treat allergic reactions** (e.g. terfenadine).
- Medicines for **the treatment of diabetes** (insulins or oral agents such as metformin).
- **Cholestyramine and colestipol**, medicines for lowering blood fat levels.
- Medicines to increase blood pressure, such as **noradrenaline**.
- **Muscle relaxing medicines**, such as tubocurarine.
- **Anti-cholinergic medicines** (medicines used to treat a variety of disorders such as gastrointestinal cramps, urinary bladder spasm, asthma, motion sickness, muscular spasms, Parkinson's disease and as an aid to anaesthesia) such as atropine and biperiden.
- **Amantadine** (medicine used to treat Parkinson’s disease and also used to treat or prevent certain illnesses caused by viruses).

- Other medicines used to treat **high blood pressure, corticosteroids, painkillers** (such as nonsteroidal anti-inflammatory drugs [NSAIDs])**, medicines to treat cancer, gout, or arthritis, and calcium supplements and/or vitamin D supplements**.
- An **ACE-inhibitor** or **aliskiren** (see also information under the headings "Do not take [nationally completed name]" and "Warnings and precautions").
- **Digoxin**, a medicine to treat heart diseases.

[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].

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

[nationally completed name] with alcohol
Avoid taking alcohol until you have talked to your doctor. Alcohol may make your blood pressure fall more and/or increase the risk of you becoming dizzy or feeling faint.

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 a 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 your liver is not working properly, the usual dose should not exceed 40 mg/12.5 mg once a day.

If you take more [nationally completed name] than you should
If you accidentally take too many tablets you may experience symptoms such as low blood pressure and rapid heartbeat. Slow heartbeat, dizziness, vomiting, reduced kidney function including kidney failure, have also been reported. Due to the hydrochlorothiazide component, markedly low blood pressure and low blood levels of potassium can also happen, which may result in nausea, sleepiness and muscle cramps and/or irregular heartbeat associated with the concomitant use of medicines such as digitalis or certain anti-arrhythmic treatments. 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 dose.

If you have 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), blistering and peeling of the top layer of skin (toxic epidermal necrolysis); these side effects are rare (may affect up to 1 in 1,000 people) or of unknown frequency (toxic epidermal necrolysis) 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. Increased incidence of sepsis has been observed with telmisartan only, however cannot be ruled out for [nationally completed name].

Possible side effects of [nationally completed name]:

Common side effects (may affect up to 1 in 10 people):
- dizziness

Uncommon side effects (may affect up to 1 in 100 people):
- decreased blood potassium levels
- anxiety
- fainting (syncope)
- sensation of tingling
- pins and needles (paraesthesia)
- feeling of spinning (vertigo)
- fast heart beat (tachycardia)
- heart rhythm disorders
- low blood pressure
- a sudden fall in blood pressure when you stand up
- shortness of breath (dyspnoea)
- diarrhea
- dry mouth
- flatulence
- back pain
- muscle spasm
- muscle pain
- erectile dysfunction (inability to get or keep an erection)
- chest pain
- increased blood uric acid levels.

Rare side effects (may affect up to 1 in 1,000 people):
- Inflammation of the lung (bronchitis)
- activation or worsening of systemic lupus erythematosus (a disease where the body's immune system attacks the body, which causes joint pain, skin rashes and fever)
- sore throat

- inflamed sinuses
- feeling sad (depression)
- difficulty falling asleep (insomnia)
- impaired vision
- difficulty breathing
- abdominal pain
- constipation
- bloating (dyspepsia)
- feeling sick (vomiting)
- inflammation of the stomach (gastritis)
- 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)
- redness of the skin (erythema)
- allergic reactions such as itching or rash
- increased sweating
- hives (urticaria)
- joint pain (arthralgia) and pain in extremities
- muscle cramps
- flu-like-illness
- pain
- low levels of sodium
- increased levels of creatinine, hepatic enzymes or creatine phosphokinase in the blood.

Side effects reported with one of the individual components may be potential side effects with [nationally completed name], even if not observed in clinical trials with this medicine.

Telmisartan
In patients taking telmisartan alone the following additional side effects have been reported:

Uncommon side effects (may affect up to 1 in 100 people):
Upper respiratory tract infection (e.g. sore throat, inflamed sinuses, common cold), urinary tract infections, deficiency in red blood cells (anaemia), high potassium levels, slow heart rate (bradycardia), kidney impairment including acute kidney failure, weakness, cough.

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), low platelet count (thrombocytopenia), increase in certain white blood cells (eosinophilia), serious allergic reaction (e.g. hypersensitivity, anaphylactic reaction, drug rash), low blood sugar levels (in diabetic patients), upset stomach, eczema (a skin disorder), arthrosis, inflammation of the tendons, decreased haemoglobin (a blood protein), somnolence.

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.

Hydrochlorothiazide
In patients taking hydrochlorothiazide alone the following additional side effects have been reported:

Common side effects (may affect up to 1 in 10 people):
Feeling sick (nausea), low blood magnesium level.

Rare side effects (may affect up to 1 in 1,000 people):
Reduction in blood platelets (thrombocytopenia), which increases risk of bleeding or bruising (small purple-red marks in skin or other tissue caused by bleeding), high blood calcium level, headache.

Very rare side effects (may affect up to 1 in 10,000 people):
Increased pH (disturbed acid-base balance) due to low blood chloride level.

Side effects of unknown frequency (frequency cannot be estimated from the available data):
Inflammation of the salivary gland, decreases in the number (or even lack) of cells in the blood, including low red and white blood cell count, serious allergic reactions (e.g. hypersensitivity, anaphylactic reaction), decreased or loss of appetite, restlessness, light-headedness, blurred or yellowing of vision, decrease in vision and eye pain (possible signs of acute myopia or acute-angle closure glaucoma), inflammation of blood vessels (vasculitis necrotising), inflamed pancreas, upset stomach, yellowing of the skin or eyes (jaundice), lupus-like syndrome (a condition mimicking a disease called systemic lupus erythematosus where the body's immune system attacks the body); skin disorders such as inflamed blood vessels in the skin, increased sensitivity to sunlight, rash, redness of the skin, blistering of the lips, eyes or mouth, skin peeling, fever (possible signs of erythema multiforme), weakness, kidney inflammation or impaired kidney function, glucose in the urine (glycosuria), fever, impaired electrolyte balance, high blood cholesterol levels, decreased blood volume, increased levels of glucose, difficulties in controlling blood/ urine levels of glucose in patients with a diagnosis of diabetes mellitus, or fat in the blood, skin and lip cancer (non-melanoma skin cancer).

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

Do not store above 30°C. Store in the original blister in order to protect from moisture.

Do not use this medicine if you notice change in appearance in any way.

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 substances are telmisartan and hydrochlorothiazide

[Invented name, 40/12.5 mg, coated tablets]
Each coated tablet contains 40 mg telmisartan and 12.5 mg hydrochlorothiazide.

[Invented name, 80/12.5 mg, coated tablets]
Each coated tablet contains 80 mg telmisartan and 12.5 mg hydrochlorothiazide.

[Invented name, 80/25 mg, coated tablets]
Each coated tablet contains 80 mg telmisartan and 25 mg hydrochlorothiazide.

The other ingredients are:
[Invented name, 40/12.5 mg, coated tablets]
Tablet core: Sodium Hydroxide, Meglumine, Povidone K25 (E1201), Lactose monohydrate, Povidone K30 (E1201), Crospovidone (type A) (E1202), Lactose anhydrous, Magnesium stearate (E572)
Coating: Polivinyl alcohol units (E1203, Polyethylene glycol (E1521), Anhydrous colloidal silica (E551), Citric acid monohydrate (E330)
Iron oxide yellow (E172), Iron oxide red (E172)

[Invented name, 80/12.5 mg, coated tablets]
Tablet core: Sodium Hydroxide, Meglumine, Povidone K25 (E1201), Lactose monohydrate, Povidone K30 (E1201), Crospovidone (type A) (E1202), Lactose anhydrous, Magnesium stearate (E572)
Coating: Polivinyl alcohol units (E1203), Polyethylene glycol (E1521), Anhydrous colloidal silica (E551), Citric acid monohydrate (E330)

[Invented name, 80/25 mg, coated tablets]
Tablet core: Sodium Hydroxide, Meglumine
Povidone K25 (E1201), Lactose monohydrate
Povidone (E1201), Crospovidone (type A) (E1202), Lactose anhydrous, Magnesium stearate
Coating: Polivinyl alcohol units (E1203, Polyethylene glycol (E1521), Anhydrous colloidal silica (E551), Citric acid monohydrate (E330), Iron oxide yellow (E172)

For further information on lactose see end of section 2

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

[Invented name, 40/12.5 mg, coated tablets]
Red, oval, biconvex coated tablet debossed with 40 on one side and with 12.5 on the other side (12.4 mm x 6.2 mm).

[Invented name, 80/12.5 mg, coated tablets]
White to off-white, oval, biconvex coated tablet debossed with 80 on one side and with 12.5 on the other side (15.4 mm x 8.0 mm).

[Invented name, 80/25 mg, coated tablets]
Yellow, oval, biconvex coated tablet debossed with 80 on one side and with 25 on the other side (15.4 mm x 8.0 mm).

Al/Al blisters containing 14, 28, 30, 56, 60, 98 and 100 coated tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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Roemenië

In het Register ingeschreven onder:
Telmisartan/hydrochloothiazide Sandoz 40 mg/12,5 mg, omhulde tabletten: RVG 111922
Telmisartan/hydrochloothiazide Sandoz 80 mg/12,5 mg, omhulde tabletten: RVG 111923
Telmisartan/hydrochloothiazide Sandoz 80 mg/25 mg, omhulde tabletten: RVG 111924

This medicinal product is authorised in the Member States of the EEA under the following names:

Nederland	Telmisartan/hydrochloothiazide Sandoz 40 mg/12,5 mg omhulde tabletten Telmisartan/hydrochloothiazide Sandoz 80 mg/12,5 mg omhulde tabletten Telmisartan/hydrochloothiazide Sandoz 80 mg/25 mg omhulde tabletten
Duitsland	Telmisartan/HCT Sandoz 40 mg/12,5 mg überzogene Tabletten Telmisartan/HCT Sandoz 80 mg/12,5 mg überzogene Tabletten Telmisartan/HCT Sandoz 80 mg/25 mg überzogene Tabletten

Deze bijsluiter is voor het laatst goedgekeurd in maart 2019.