

PATIENT INFORMATION LEAFLET

Telmisartan/Hydrochlorothiazide 40 mg/12.5 mg tablets

Telmisartan/Hydrochlorothiazide 80 mg/12.5 mg tablets

Telmisartan/Hydrochlorothiazide 80 mg/25 mg tablets

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.

What is in this leaflet:

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

1. What Telmisartan and Hydrochlorothiazide Tablets is and what it is used for

Telmisartan and Hydrochlorothiazide Tablets is a combination of two active substances, telmisartan and hydrochlorothiazide in one tablet. Both 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 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 and Hydrochlorothiazide Tablets 80 mg/25 mg:

Telmisartan and Hydrochlorothiazide Tablets 80 mg / 25 mg is used to treat high blood pressure (essential hypertension) in adults whose blood pressure is not adequately controlled by Telmisartan and Hydrochlorothiazide Tablets 80 mg/12.5 mg or in patients who have been previously stabilised by telmisartan and hydrochlorothiazide given separately.

Telmisartan and Hydrochlorothiazide Tablets 80 mg/12.5 mg:

Telmisartan and Hydrochlorothiazide Tablets 80 mg/12.5 mg is used to treat high blood pressure (essential hypertension) in adults whose blood pressure is not controlled enough when telmisartan is

used alone.

Telmisartan and Hydrochlorothiazide Tablets 40 mg/12.5 mg:

Telmisartan and Hydrochlorothiazide Tablets 40 mg/12.5 mg is used to treat high blood pressure (essential hypertension) in adults whose blood pressure is not controlled enough when telmisartan is used alone.

2. What you need to know before you take Telmisartan and Hydrochlorothiazide Tablets

Do not take Telmisartan and Hydrochlorothiazide Tablets

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

Warnings and precautions

Talk to your doctor 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.
- Renalartery 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 ingredient 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 and Hydrochlorothiazide Tablets. This can lead to permanent vision loss, if not treated.

You must tell your doctor if you think you are (or might become) pregnant. Telmisartan and Hydrochlorothiazide 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).

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 Telmisartan and Hydrochlorothiazide Tablets.

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

Children and adolescents

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

Other medicines and Telmisartan and Hydrochlorothiazide Tablets:

Tell your 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 medications or take other precautions. In some cases, you may have to stop taking one of the medicines. This applies especially to the medicines below taken at the same time with Telmisartan and Hydrochlorothiazide Tablets:

- 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.
- Potassium-sparing diuretics, potassium supplements, salt substitutes containing potassium ACE inhibitors that may increase blood potassium levels.
- Heart medicines (e.g. digoxin) or medicines to control the rhythm of your heart (e.g. quinidine, disopyramide).
- Medicines used for mental disorders (e.g. thioridazine, chlorpromazine, levomepromazine).
- Other medicines used to treat high blood pressure, steroids, painkillers, medicines to treat cancer, gout, or arthritis, and vitamin D supplements.

Telmisartan and Hydrochlorothiazide Tablets may increase the blood pressure lowering effect of other medicines and you should consult with your doctor if you need to adjust the dose of your other medicine while taking Telmisartan and Hydrochlorothiazide Tablets.

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

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 and Hydrochlorothiazide 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 and Hydrochlorothiazide Tablets.

Telmisartan and Hydrochlorothiazide Tablets is not recommended during 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 and Hydrochlorothiazide 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.

Driving and using machines

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

Telmisartan and Hydrochlorothiazide Tablets contains milk sugar (lactose) and sorbitol.

If you are intolerant to some sugars, consult your doctor before taking Telmisartan and Hydrochlorothiazide Tablets.

3. How to take Telmisartan and Hydrochlorothiazide Tablets

Always take Telmisartan and Hydrochlorothiazide Tablets exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose of Telmisartan and Hydrochlorothiazide Tablets is one tablet a day. Try to take the tablet at the same time each day.

You can take Telmisartan and Hydrochlorothiazide 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 and Hydrochlorothiazide Tablets every day until your doctor tells you otherwise.

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

If you take more Telmisartan and Hydrochlorothiazide 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 and Hydrochlorothiazide 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 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. Increased incidence of sepsis has been observed with telmisartan only, however cannot be ruled out for Telmisartan and Hydrochlorothiazide Tablets.

Possible side effects of Telmisartan and Hydrochlorothiazide Tablets:

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), diarrhoea, 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, inflammation of the stomach (gastritis), abnormal liver function (Japanese patients are more likely to experience these 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, increased levels of uric acid, low levels of sodium, increased levels of creatinine, hepatic enzymes or creatine phosphokinase in the blood.

Adverse reactions reported with one of the individual components may be potential adverse reactions with Telmisartan and Hydrochlorothiazide Tablets, even if not observed in clinical trials with this product.

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: Side effects of unknown frequency (frequency cannot be estimated from the available data):

Inflammation of the salivary gland, decreases in the number of cells in the blood, including low red and white blood cell count, low platelet count (thrombocytopenia), 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-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, or blistering and peeling of the top layer of skin (toxic epidermal necrolysis), 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, or fat in the blood. If you get any of the side effects, talk to your doctor or pharmacist.

This includes any possible side effects not listed in this leaflet.

5. How to store Telmisartan and Hydrochlorothiazide 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.

This medicine does not require any special temperature storage conditions. You should store your medicine in the original package in order to protect the tablets from moisture.

Occasionally, the outer layer of the blister pack separates from the inner layer between the blister pockets. You do not need to take any action if this happens.

Do not throw away any medicines via waste water 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 and Hydrochlorothiazide Tablets contains

The active substances are telmisartan and hydrochlorothiazide. Each tablet contains 80 mg telmisartan and 25 mg hydrochlorothiazide.

The other ingredients are Meglumine, Sodium Hydroxide, Povidone, Polysorbate, Mannitol, Magnesium Stearate, Lactose Monohydrate, Microcrystalline Cellulose PH 102, Sodium Starch Glycolate & Lake Sunset Yellow

What Telmisartan and Hydrochlorothiazide Tablets looks like and contents of the pack 10 tablets are packed in plain Aluminium blister foil (lid foil) one side and printed aluminium foil on another side in the form of blister pack (10's). Three blister packs are further packed into printed carton along with instruction for use.

7. MARKETING AUTHORISATION HOLDER:

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