Package Leaflet: Information for the patient

Telmisartan and Hydrochlorothiazide 80 mg/12.5 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. See section 4.

What is in this leaflet

1. What Telmisartan and Hydrochlorothiazide tablets are and what they are used for

Telmisartan and Hydrochlorothiazide tablets are 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 your blood pressure to verify if it is within the normal range.

Telmisartan and Hydrochlorothiazide tablets are used to treat high blood pressure (essential hypertension) in adults whose blood pressure is not controlled enough when either telmisartan or hydrochlorothiazide is used alone.
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 and Hydrochlorothiazide tablets

Do not take Telmisartan and Hydrochlorothiazide tablets

- If you are allergic to telmisartan or any of the 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 taking this medicine in early pregnancy – see 'Pregnancy and breast-feeding'.)
- 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 you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product

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

Warnings and precautions
Talk to your doctor before taking this medicine 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 dialysis).
- 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.
- 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.

The active ingredient hydrochlorothiazide can cause an unusual reaction, resulting in a decrease in vision and eye pain. These could be symptoms of fluid accumulation in the vascular layer of the eye (choroidal effusion) or 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. If you earlier have had a penicillin or sulfonamide allergy, you can be at higher risk of developing this.

You must tell your doctor if you think you are (or might become) **pregnant**. Telmisartan and Hydrochlorothiazide tablets are not recommended in early pregnancy, and must not be taken if you are more than 3 months pregnant, as they may cause serious harm to your baby if used at that stage (see 'Pregnancy and breast-feeding').
Treatment with hydrochlorothiazide may cause an electrolyte imbalance in your body. Typical symptoms of fluid or **electrolyte imbalance** include dry mouth, weakness, lethargy (sluggishness), 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, talk to your doctor.

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 this medicine in children and adolescents up to the age of 18 years is not recommended.

Other medicines and Telmisartan and Hydrochlorothiazide 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 when 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 (for example castor oil),corticosteroids (for example 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 (water tablets), potassium supplements, salt substitutes containing potassium, ACE inhibitors (type of blood pressure tablets) that may increase blood potassium levels.
- **Heart medicines** (for example digoxin) or medicines to control the rhythm of your heart (for example quinidine, disopyramide).
- Medicines used for **mental disorders** (for example 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. 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 tablet may be **reduced** when you take NSAIDs (non steroidal anti-inflammatory medicines, for example aspirin or ibuprofen).

Telmisartan and Hydrochlorothiazide tablets with food, drink and alcohol
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 this medicine every day until your doctor tells you otherwise.

Pregnancy, breast-feeding and fertility
Pregnancy
You must tell your doctor if you are pregnant, think you may be pregnant or are planning to have a baby. 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. This medicine 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 and Hydrochlorothiazide tablets are not recommended for mothers who are breast-feeding. 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 they are treated for high blood pressure. If you feel dizzy or tired, do not drive or operate machinery.

Telmisartan and Hydrochlorothiazide tablets contain lactose and mannitol
This medicine contains milk sugar (lactose) and mannitol. 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 this medicine 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 your 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 this medicine 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.
Use in children and adolescents
The use of this medicine in children and adolescents up to the age of 18 years is not recommended.

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 a forgotten dose.
If you stop taking Telmisartan and Hydrochlorothiazide tablets
Check with your doctor before you start or stop taking this medicine
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:
Stop taking this medicine and 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 (may affect up to 1 in 10 people)
Dizziness

Uncommon (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 (wind),
- back pain,
- muscle spasm,
- muscle pain,
- erectile dysfunction (inability to get or keep an erection),
- chest pain,
- increased blood uric acid levels.

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

Rare (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 (for example 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 (sleepiness).

Very rare (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:

Not known (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 (for example hypersensitivity, anaphylactic reaction), decreased or loss of appetite, restlessness, light-headedness, blurred or yellowing of vision, inflammation of blood vessels (vasculitis ecrotising), inflamed pancreas (pancreatitis), 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, balance (imbalance of minerals in the body), high blood cholesterol levels, decreased blood volume, increased levels of glucose, or fat in the blood, skin and lip cancer (Non-melanoma skin cancer)
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

Decrease in vision or pain in your eyes due to high pressure (possible signs of fluid accumulation in the vascular layer of the eye (choroidal effusion) or acute angle-closure glaucoma)

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: 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 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 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 wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Telmisartan and Hydrochlorothiazide tablets contain

- The active substances are telmisartan and hydrochlorothiazide. Each tablet contains 80 mg telmisartan and 12.5 mg hydrochlorothiazide.
- The other ingredients are mannitol, sodium hydroxide, meglumine, povidone k-25, sodium stearyl fumarate, lactose monohydrate, magnesium stearate, colour blend including lactose monohydrate and iron oxide red.

What Telmisartan and Hydrochlorothiazide tablets look like and contents of the pack
Telmisartan and Hydrochlorothiazide 80 mg/12.5 mg tablets are oblong shaped, biconvex, bilayered, uncoated tablets with one white to off-white colour layer and one mottled pink colour layer debossed with 'L200'. The white to off-white color layer may contain pink colour specks.

Telmisartan and Hydrochlorothiazide 80 mg/12.5 mg tablets are available in blisters pack containing 10 or 28 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder
Somex Pharma, Ilford, Essex. IG3 8BS. UK

Manufacturer
Somex Pharma, Ilford, Essex. IG3 8RA. UK

This leaflet was last revised in 05/2020

520 mm
150 mm
Front Side

520 mm
150 mm
Back Side

Product : Telmisartan HCTZ Tablets 40 /12.5 mg
Type : Pack Insert
Size : 150 x 520 mm
Date :06.05.2020
Pharmacode :