Package leaflet: Information for the user

Telmisartan/Hydrochlorothiazide 40 mg/12.5 mg tablets
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 Telmisartan/Hydrochlorothiazide is and what it is used for
2. What you need to know before you take Telmisartan/Hydrochlorothiazide
3. How to take Telmisartan/Hydrochlorothiazide
4. Possible side effects
5. How to store Telmisartan/Hydrochlorothiazide
6. Contents of the pack and other information

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

Telmisartan/Hydrochlorothiazide 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.

Telmisartan/Hydrochlorothiazide 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/Hydrochlorothiazide

Do not take Telmisartan/Hydrochlorothiazide
- 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 Telmisartan Hydrochlorothiazide 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 Telmisartan/ Hydrochlorothiazide.

Warnings and precautions
Talk to your doctor before taking Telmisartan/Hydrochlorothiazide 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.
- 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 Telmisartan/ Hydrochlorothiazide.
- If you experienced breathing or lung problems (including inflammation or fluid in the lungs) following hydrochlorothiazide intake in the past. If you develop any severe shortness of breath or difficulty breathing after taking Telmisartan/Hydrochlorothiazide, seek medical attention immediately.
- The active substance 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/Hydrochlorothiazide. This can lead to permanent vision impairment, if not treated. If you earlier have had a penicillin or sulfonamide allergy, you can be at higher risk of developing this.

Talk to your doctor before taking Telmisartan/Hydrochlorothiazide, 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/Hydrochlorothiazide".
- digoxin.

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

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

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

Other medicines and Telmisartan/Hydrochlorothiazide

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 medications 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/Hydrochlorothiazide:

- 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, ciclosporin (an immunosuppressant drug) and other medicinal products such as heparin sodium (an anticoagulant).
- Medicines that are affected by changes of the blood potassium level such as 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) and other medicines such as 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.
- Calcium supplements and/or vitamin D supplements.
- 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 non-steroidal anti-inflammatory drugs [NSAIDs]), medicines to treat cancer, gout, or arthritis.
- If you are taking an ACE-inhibitor or aliskiren (see also information under the headings "Do not take Telmisartan/ Hydrochlorothiazide" and "Warnings and precautions").
- Digoxin.

Telmisartan/Hydrochlorothiazide 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/ Hydrochlorothiazide.

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

Telmisartan/Hydrochlorothiazide with food and alcohol

You can take Telmisartan/Hydrochlorothiazide with or without food.
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 Telmisartan/Hydrochlorothiazide before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Telmisartan/ Hydrochlorothiazide. Telmisartan/ Hydrochlorothiazide 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/ Hydrochlorothiazide 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/ Hydrochlorothiazide. If you feel dizzy or tired, do not drive or operate machinery.

Telmisartan/ Hydrochlorothiazide 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 Telmisartan/Hydrochlorothiazide

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

The recommended dose Telmisartan/ Hydrochlorothiazideis one tablet a day. Try to take the tablet at the same time each day. You can take Telmisartan/ Hydrochlorothiazide with or without food. The tablets should be swallowed with some water or other non-alcoholic drink. It is important that you take Telmisartan/ Hydrochlorothiazide 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 Telmisartan/ Hydrochlorothiazide 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 medicinal products such as digitalis or certain anti-arrhythmic treatments. Contact your doctor, pharmacist, or your nearest hospital emergency department immediately.

If you forget to take Telmisartan/ Hydrochlorothiazide
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 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); 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 it can not be ruled out for Telmisartan/ Hydrochlorothiazide.

Possible side effects of Telmisartan/ Hydrochlorothiazide:

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, 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 1000 people):
Inflammation of the lungs (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), 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.

Adverse reactions reported with one of the individual components may be potential adverse reactions with Telmisartan/ Hydrochlorothiazide, 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 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 (may affect up to 1 in 1000 people):
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(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 (may affect up to 1 in 10 people):
Feeling sick (nausea), low blood magnesium level.

Rare (may affect up to 1 in 1,000 people):
Reduction in blood platelets, 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 (may affect up to 1 in 10,000 people):
Increased pH (disturbed acid-base balance) due to low blood chloride level.
Acute respiratory distress (signs include severe shortness of breath, fever, weakness, and confusion).

Not known (frequency cannot be estimated from the available data)
Skin and lip cancer (Non-melanoma skin cancer), 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 due to high pressure (possible signs of fluid accumulation in the vascular layer of the eye (choroidal effusion), 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 blood levels of glucose, difficulties in controlling blood/ urine levels of glucose in patients with a diagnosis of diabetes mellitus, or fat in the blood.

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 HPRA Pharmacovigilance Website: www.hpra.ie
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Telmisartan/Hydrochlorothiazide

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, blister or bottle label after "EXP". The expiry date refers to the last day of that month.

For Al/Al blisters and HDPE tablet container
This medicine does not require any special storage conditions.

For Al/PVC/PVDC blister
Do not store above 30ºC.

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/Hydrochlorothiazide contains
- The active substances are telmisartan and hydrochlorothiazide. Each tablet contains 40 mg telmisartan and 12.5 mg hydrochlorothiazide.
- The other ingredients are magnesium stearate (E470b), potassium hydroxide, meglumine, povidone, sodium starch glycolate (type A), microcrystalline cellulose, mannitol (E421).

What Telmisartan/Hydrochlorothiazide looks like and contents of the pack
Telmisartan/ Hydrochlorothiazide 40 mg/12.5 mg tablets are white or almost white, 6.55 x 13.6 mm oval-shaped and biconvex tablets marked with "TH" on one side.

Pack sizes
Al/Al blister packs: 14, 28, 30, 56, 84, 90 and 98 tablets
Al/PVC/PVDC blister packs: 28, 56, 84, 90 and 98 tablets
Tablet containers: 30, 90 and 250 tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Accord Healthcare Ireland Limited
Euro House
Euro Business Park
Little Island
Cork
T45 K857
Ireland

Manufacturer
Actavis Ltd
BLB016
Bulebel Industrial Estate
Zejtun ZTN 3000
Malta

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