Package leaflet: Information for the user

Telmisartan/Hydrochlorothiazide Rowa 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 Rowa is and what it is used for

Telmisartan/Hydrochlorothiazide Rowa 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 blockers. 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 Rowa 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 Rowa

Do not take Telmisartan/Hydrochlorothiazide Rowa
- if you are allergic to telmisartan or any other of the 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 Rowa 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 or anuria (less than 100 ml urine per day).
- 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 Rowa.

Warnings and precautions

Talk to your doctor before taking Telmisartan/Hydrochlorothiazide Rowa 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 haemofiltration.
- 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 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/Hydrochlorothiazide Rowa. 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 Telmisartan/Hydrochlorothiazide Rowa.

Talk to your doctor if you experience abdominal pain, nausea, vomiting or diarrhoea after taking Telmisartan/Hydrochlorothiazide Rowa. Your doctor will decide on further treatment. Do not stop taking Telmisartan/Hydrochlorothiazide Rowa on your own.

Talk to your doctor before taking Telmisartan/Hydrochlorothiazide Rowa

- 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 Rowa".
- if you are taking digoxin
- 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 Rowa seek medical attention immediately.

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

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

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

Other medicines and Telmisartan/Hydrochlorothiazide Rowa
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 to 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 Rowa:

- 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.
- Iodinated contrast product used in the context of an imaging examination
- 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 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 nonsteroidal 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 Rowa” and “Warnings and precautions”).
- Digoxin.

Telmisartan/Hydrochlorothiazide Rowa 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 Rowa.

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

Telmisartan/Hydrochlorothiazide Rowa with food and alcohol
You can take Telmisartan/Hydrochlorothiazide Rowa 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 Rowa 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 Rowa.
Telmisartan/Hydrochlorothiazide Rowa 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 Rowa 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 faint or feel like everything around you is spinning or tired when taking Telmisartan/Hydrochlorothiazide Rowa. If you experience any of these effects, do not drive or operate machinery.

Telmisartan/Hydrochlorothiazide Rowa contains milk sugar **(lactose)**
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Telmisartan/Hydrochlorothiazide Rowa 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 Rowa

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/Hydrochlorothiazide Rowa is one tablet a day. Try to take a tablet at the same time each day. You can take Telmisartan/Hydrochlorothiazide Rowa with or without food. The tablets should be swallowed whole with some water or other non-alcoholic drink. It is important that you take Telmisartan/Hydrochlorothiazide Rowa every day until your doctor tells you otherwise.

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

If you take more Telmisartan/Hydrochlorothiazide Rowa 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 Telmisartan/Hydrochlorothiazide Rowa

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 including fatal outcome); 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 very rare (toxic epidermal necrolysis may affect up to 1 in 10 000 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/Hydrochlorothiazide Rowa.

Possible side effects of Telmisartan/Hydrochlorothiazide Rowa:

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 1000 people):
Inflammation of the airways to the lung (bronchitis), sore throat, inflamed sinuses, increased level of uric acid, low sodium level, feeling sad (depression), difficulty falling asleep (insomnia), ,sleep disorder, impaired vision, blurred 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 (leg pain), muscle cramps, 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), flu-like-illness, pain, 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 Rowa, 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, infection of urinary bladder, deficiency in red blood cells (anaemia), high potassium levels, slow heart rate (bradycardia), cough, kidney impairment including acute kidney failure, weakness.

Rare side effects (may affect up to 1 in 1,000 people):
Low platelet count (thrombocytopenia), increase in certain white blood cells (eosinophilia), serious allergic reaction (e.g. hypersensitivity, anaphylactic reaction,), low blood sugar levels (in diabetic patients), somnolence, upset stomach, eczema (a skin disorder), drug eruption, toxic skin eruption, tendon pain (tendonitis-like symptoms),, decreased haemoglobin (a blood protein).

Very rare side effects (may affect up to 1 in 10,000 people):

Progressive scarring of lung tissue (interstitial lung disease)**.

Not known (frequency cannot be estimated from the available data):
Intestinal angioedema: a swelling in the gut presenting with symptoms like abdominal pain, nausea, vomiting, and diarrhoea has been reported after the use of similar products.

*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:

Very common side effects (may affect more than 1 in 10 people)
Elevated blood fat levels

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

Uncommon side effects (may affect up to 1 in 100 people)
Acute kidney failure.

Rare side effects (may affect up to 1 in 1,000 people):
Low platelet count (thrombocytopenia), which increases risk of bleeding or bruising (small purple-red marks in skin or other tissue caused by bleeding), high blood calcium level, high blood sugar level, headache, abdominal discomfort, yellowing of the skin or eyes (jaundice), excess of biliary substances in the blood (cholestasis), photosensitivity reaction, uncontrolled blood levels of glucose in patients with a diagnosis of diabetes mellitus, sugars in the urine (glucosuria) .

Very rare side effects (may affect up to 1 in 10,000 people):
Abnormal breakdown of red blood cells (haemolytic anaemia), inability of the bone marrow to work properly, reduction of white blood cells (leukopenia, agranulocytosis), serious allergic reactions (e.g. hypersensitivity), increased pH due to low blood chloride level (disturbed acid-base balance, alkalosis hypochloraemic). Acute respiratory distress (signs include severe shortness of breath, fever, weakness, and confusion), inflammation of the pancreas, lupus-like syndrome (a condition mimicking a disease called systemic lupus erythematosus where the body's immune system attacks the body), inflammation of blood vessels (vasculitis necrotising).

Not known (frequency cannot be estimated from the available data): Inflammation of the salivary gland, skin and lip cancer (non-melanoma skin cancer), blood cell deficiency (aplastic anaemia), decrease in vision and eye pain (possible signs of fluid accumulation in the vascular layer of the eye (choroidal effusion) or acute-angle closure glaucoma),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 impairment.

Low levels of sodium accompanied by symptoms relating to the brain or nerves (feeling sick, progressive disorientation, lack of interest or energy) occurs in isolated cases.

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 Rowa

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. Store in the original package in order to protect from light and moisture. Remove your Telmisartan/Hydrochlorothiazide Rowa tablet from the blister only directly prior to intake.

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 Rowa contains

The active substances are telmisartan and hydrochlorothiazide. Each tablet contains 40 mg telmisartan and 12.5 mg hydrochlorothiazide.
The other ingredients are Mannitol (E421), Povidone (Povidone K 25) (E1201), Crospovidone (E1202), Magnesium Stearate (E572), Meglumine, Sodium Hydroxide (E524), Lactose Monohydrate, Cellulose Microcrystalline (E460), Hypromellose (Hydroxypropylmethylcellulose) (E464), Carboxymethyl starch sodium from potato starch (Type A), and Ferric Oxide Yellow (10E 172).

What Telmisartan/Hydrochlorothiazide Rowa looks like and contents of the pack

Telmisartan/Hydrochlorothiazide Rowa 40 mg/12.5 mg tablets are round bilayer tablets with white and yellow color.
Telmisartan/Hydrochlorothiazide Rowa is available in blisters packs containing 7, 10, 14, 28, 28x1, 30, 30x1, 50, 56, 84, 90, 90x1, 98, 100, 112, 126, 140, 154, 168, 182, 196 tablets.

Not all pack sizes may be available in your country.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder
Rowa Pharmaceuticals Ltd.
Newtown
Bantry
Co Cork
Ireland.

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder

Manufacturer
Laboratorios Liconsa, S.A.
Avda. Miralcampo, nº 7
Poligono Industrial Miralcampo
19200 Azuqueca de Henares (Guadalajara)
Spain.

This medicinal product is authorised in the Member States of the European Economic Area under the following names:

Netherlands:	Telmisartan/ Hydrochloorthiazide Liconsa
France:	Telmisartan/Hydrochlorothiazide Liconsa
Belgium:	Telmisartan/Hydrochlorothiazide Liconsa
Ireland:	Telmisartan/Hydroclorothiazide Rowa
Bulgaria:	Telmimed Plus

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Detailed information on this medicine is available on the website of the HPRA. www.hpra.ie