PACKAGE LEAFLET: INFORMATION FOR THE USER

Telmisartan/Hydrochlorothiazide Chemo Ibérica 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 yourdoctor 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 yourdoctor 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 Chemo Ibérica is and what it is used for

Telmisartan/Hydrochlorothiazide Chemo Ibérica 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 Chemo Ibérica is used to treat high blood pressure (essential hypertension) in patients whose blood pressure is not controlled enough when either telmisartan or hydrochlorothiazide is used alone.

2. What you need to know before you take Telmisartan/Hydrochlorothiazide Chemo Ibérica

Do not take Telmisartan/Hydrochlorothiazide Chemo Ibérica
- if you are allergic (hypersensitive) to telmisartan or any other ingredients of this medicine (listed in section 6).
- if you are allergic (hypersensitive) 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 Chemo Ibérica 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 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 Chemo Ibérica.

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.
-Renal artery stenosis (narrowing of the blood vessels to one or both kidneys). -Liver disease. -Heart trouble. -Diabetes.
- 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.
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– 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 Chemo Ibérica.
– Talk to your doctor, pharmacist, or nurse before taking Telmisartan/Hydrochlorothiazide Chemo Ibérica. If you experience a decrease in vision or 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 Chemo Ibérica. 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

Talk to your doctor before taking Telmisartan/Hydrochlorothiazide Chemo Ibérica
- 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 Chemo Ibérica"
- if you are taking digoxin.

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

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

Children and adolescents

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

Other medicines and Telmisartan/Hydrochlorothiazide Chemo Ibérica
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. Your doctor may need to change the dose and/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 Chemo Ibérica:

- 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 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 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 Chemo Ibérica” and “Warnings and precautions”)
- Digoxin.

Telmisartan/Hydrochlorothiazide Chemo Ibérica 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 Chemo Ibérica.

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

Telmisartan/Hydrochlorothiazide Chemo Ibérica with food and alcohol

You can take Telmisartan/Hydrochlorothiazide Chemo Ibérica 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 Chemo Ibérica 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 Chemo Ibérica. Telmisartan/Hydrochlorothiazide Chemo Ibérica 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/Hydrochlorothiazide Chemo Ibérica 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 Chemo Ibérica. If you feel dizzy or tired, do not drive or operate machinery.

Important information about some of the ingredients of Telmisartan/Hydrochlorothiazide Chemo Ibérica
Telmisartan/Hydrochlorothiazide Chemo Ibérica 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 medicinal product.

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 Chemo Ibérica

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

The usual dose of Telmisartan/Hydrochlorothiazide Chemo Ibérica is one tablet a day. Try to take a tablet at the same time each day. You can take Telmisartan/Hydrochlorothiazide Chemo Ibérica 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 Chemo Ibérica 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 Chemo Ibérica 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 drugs 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 Chemo Ibérica

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 medicinecan 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 medicineand see their doctor immediately. If these effects are not treated they could be fatal. Increased incidence od sepsis has been observed with telmisartan only, however can not be ruled out for Telmisartan/Hydrochlorothiazide Chemo Ibérica.

Possible side effects of Telmisartan/Hydrochlorothiazide Chemo Ibérica:

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 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 with Telmisartan/Hydrochlorothiazide Chemo Ibérica, 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 to 10 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):

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, 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, skin and lip cancer (non-melanoma skin cancer), 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 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), 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.
If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Telmisartan/Hydrochlorothiazide Chemo Ibérica

Keep this medicine out of the sight and reach of children.

Do not use this medicineafter the expiry date which is stated on the carton after "EXP". The expiry date refers to the last day of that month.

You should store your medicine in the original (sealed) package in order to protect the tablets from moisture and light.

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 Chemo Ibérica 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 (Hydroxipropylmethylcellulose) (E464), Carboxymethyl starch sodium from potato starch Type Aand Ferric Oxide Yellow (10E 172).

What Telmisartan/Hydrochlorothiazide Chemo Ibérica looks like and contents of the pack

Telmisartan/Hydrochlorothiazide Chemo Ibérica 40 mg/12.5 mg tablets are round bilayer tablets with white and yellow color. Telmisartan/Hydrochlorothiazide Chemo Ibérica 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
Laboratorios Liconsa S.A.
C/ Dulcinea S/N,
28805 Alcalá de Henares, Madrid
Spain

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 EEA under the following names:

The Netherlands: Telmisartan/Hydrocloorthiazide Chemo Ibérica 40/12.5 mg tabletten
Austria: Telmisartan/HCT +pharma 40 mg/12,5 mg Tabletten
Belgium: Telmisartan/Hydrochlorothiazide Chemo Ibérica 40/12,5 mg comprimés
Luxemburg: Telmisartan/Hydrochlorothiazide Chemo Ibérica 40/12,5 mg tablets
Germany. Telmisartan/Hydrochlorothiazide AXiromed 40/12,5 mg tablets
Spain: Telmisartán / Hidroclorotiazida Stada 40/12,5 mg comprimidos EFG
France: Telmisartan/Hydrochlorothiazide Chemo Ibérica 40/12,5 mg tablets
Ireland: Telmisartan/Hydrochlorothiazide Chemo Ibérica 40/12,5 mg tablets
Portugal: Telmisartan/Hydrochlorothiazide Chemo Ibérica 40/12,5 mg comprimidos

This leaflet was last revised in 06/2021

<Other sources of information> Detailed information on this medicine is available on the European Medicines Agency (EMA) web site: http://www.ema.europa.eu/

PACKAGE LEAFLET: INFORMATION FOR THE USER

Telmisartan/Hydrochlorothiazide Chemo Ibérica 80 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 Chemo Ibérica is and what it is used for

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– 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 Chemo Ibérica is used to treat high blood pressure (essential hypertension) in patients whose blood pressure is not controlled enough when either telmisartan or hydrochlorothiazide is used alone.

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- if you are allergic (hypersensitive) to telmisartan or any other ingredients of this medicine (listed in section 6).
- if you are allergic (hypersensitive) 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 Chemo Ibérica 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 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 Chemo Ibérica.

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-Kidney disease or kidney transplant.
-Renal artery stenosis (narrowing of the blood vessels to one or both kidneys). -Liver disease. -Heart trouble. -Diabetes.
- 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 Chemo Ibérica.
– Talk to your doctor, pharmacist, or nurse before taking Telmisartan/Hydrochlorothiazide Chemo Ibérica.If you experience a decrease in vision or 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 a week of taking Telmisartan/Hydrochlorothiazide Chemo Ibérica. 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

Talk to your doctor before taking Telmisartan/Hydrochlorothiazide Chemo Ibérica

- 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 Chemo Ibérica"
- if you are taking digoxin.

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

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

Children and adolescents

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

Other medicines and Telmisartan/Hydrochlorothiazide Chemo Ibérica
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. Your doctor may need to change the dose and/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 Chemo Ibérica:

- 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 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 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 Chemo Ibérica” and “Warnings and precautions”)
- Digoxin.

Telmisartan/Hydrochlorothiazide Chemo Ibérica 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 Chemo Ibérica.

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

Telmisartan/Hydrochlorothiazide Chemo Ibérica with food and alcohol

You can take Telmisartan/Hydrochlorothiazide Chemo Ibérica 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 Chemo Ibérica 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 Chemo Ibérica. Telmisartan/Hydrochlorothiazide Chemo Ibérica 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/Hydrochlorothiazide Chemo Ibérica 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 Chemo Ibérica. If you feel dizzy or tired, do not drive or operate machinery.

Important information about some of the ingredients of Telmisartan/Hydrochlorothiazide Chemo Ibérica
Telmisartan/Hydrochlorothiazide Chemo Ibérica 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 medicinal product.

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 Chemo Ibérica

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

The usual dose of Telmisartan/Hydrochlorothiazide Chemo Ibérica is one tablet a day. Try to take the tablet at the same time each day. You can take Telmisartan/Hydrochlorothiazide Chemo Ibérica 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 Chemo Ibérica 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 Chemo Ibérica 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 drugs 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 Chemo Ibérica

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, Telmisartan/Hydrochlorothiazide Chemo Ibérica 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 can not be ruled out for Telmisartan/Hydrochlorothiazide Chemo Ibérica.

Possible side effects of Telmisartan/Hydrochlorothiazide Chemo Ibérica:

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, inflamation 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 with Telmisartan/Hydrochlorothiazide Chemo Ibérica, 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 to 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 to 1,000 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 side effects (may affect up to 1 to 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, 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, skin and lip cancer (non-melanoma skin cancer), 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 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), 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.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Telmisartan/Hydrochlorothiazide Chemo Ibérica

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.

.You should store your medicine in the original (sealed)package in order to protect the tablets from moisture and light.

Do not throw away any medicinesvia 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 Chemo Ibérica contains

The active substances are telmisartan and hydrochlorothiazide. Each tablet contains 80 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 (Hydroxipropylmethylcellulose) (E464), Carboxymethyl starch sodium from potato starch Type A and Ferric Oxide Red (30E 172).

What Telmisartan/Hydrochlorothiazide Chemo Ibérica looks like and contents of the pack

Telmisartan/Hydrochlorothiazide Chemo Ibérica 80 mg/12.5 mg tablets are round bilayer tablets with white and pinkcolor. Telmisartan/Hydrochlorothiazide Chemo Ibérica is available in blisters packs containing 7, 10, 14, 28, 28x1, 30, 30x1m 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
Laboratorios Liconsa S.A.
C/ Dulcinea S/N,
28805 Alcalá de Henares, Madrid
Spain

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 EEA under the following names:

The Netherlands: Telmisartan/Hydrocloorthiazide Chemo Ibérica 80/12.5 mg tabletten
Austria: Telmisartan/HCT +pharma 80 mg/12,5 mg Tabletten
Belgium: Telmisartan/Hydrochlorothiazide Chemo Ibérica 80/12,5 mg comprimés
Bulgaria: Telmisartan/Hydrochlorothiazide Chemo Ibérica 80/12,5 mg tablets
Luxemburg: Telmisartan/Hydrochlorothiazide Chemo Ibérica 80/12,5 mg tablets
Germany. Telmisartan/Hydrochlorothiazide AXiromed 80/12,5 mg tablets
Spain: Telmisartán / Hidroclorotiazida Stada 80/12,5 mg comprimidos EFG
France: Telmisartan/Hydrochlorothiazide Chemo Ibérica 80/12,5 mg tablets
Ireland: Telmisartan/Hydrochlorothiazide Chemo Ibérica 80/12,5 mg tablets
Portugal: Telmisartan/Hydrochlorothiazide Chemo Ibérica 80/12,5 mg comprimidos

This leaflet was last revised in 06/2021

<Other sources of information>

Detailed information on this medicine is available on the European Medicines Agency (EMA) web site: http://www.ema.europa.eu/

PACKAGE LEAFLET: INFORMATION FOR THE USER

Telmisartan/Hydrochlorothiazide Chemo Ibérica 80 mg/25 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 Chemo Ibérica is and what it is used for

Telmisartan/Hydrochlorothiazide Chemo Ibérica 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 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 Chemo Ibérica is used to treat high blood pressure (essential hypertension) in patients whose blood pressure is not controlled enough when either telmisartan or hydrochlorothiazide is used alone.

2. What you need to know before you take Telmisartan/Hydrochlorothiazide Chemo Ibérica

Do not take Telmisartan/Hydrochlorothiazide Chemo Ibérica
- if you are allergic (hypersensitive) to telmisartan or any other ingredients of this medicine (listed in section 6).
- if you are allergic (hypersensitive) 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 Chemo Ibérica 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 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 Chemo Ibérica.

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.
-Renal artery stenosis (narrowing of the blood vessels to one or both kidneys). -Liver disease. -Heart trouble. -Diabetes.
- 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 Chemo Ibérica.
– Talk to your doctor, pharmacist, or nurse before taking Telmisartan/Hydrochlorothiazide Chemo Ibérica. If you experience a decrease in vision or 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 a week of taking Telmisartan/Hydrochlorothiazide Chemo Ibérica. 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

Talk to your doctor before taking Telmisartan/Hydrochlorothiazide Chemo Ibérica

- 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 Chemo Ibérica"
- if you are taking digoxin.

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

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

Children and adolescents

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

Other medicines and Telmisartan/Hydrochlorothiazide Chemo Ibérica
Tell your doctor or pharmacist if you are taking ,have recently taken or might take any other medicines, including medicines obtained without a prescription. Your doctor may need to change the dose and/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 Chemo Ibérica:

- 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 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 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 Chemo Ibérica” and “Warnings and precautions”)
- Digoxin.

Telmisartan/Hydrochlorothiazide Chemo Ibérica 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 Chemo Ibérica.

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

Telmisartan/Hydrochlorothiazide Chemo Ibérica with food and alcohol

You can take Telmisartan/Hydrochlorothiazide Chemo Ibérica 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 Chemo Ibérica 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 Chemo Ibérica. Telmisartan/Hydrochlorothiazide Chemo Ibérica 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/Hydrochlorothiazide Chemo Ibérica 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 Chemo Ibérica. If you feel dizzy or tired, do not drive or operate machinery.

Important information about some of the ingredients of Telmisartan/Hydrochlorothiazide Chemo Ibérica
Telmisartan/Hydrochlorothiazide Chemo Ibérica 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 medicinal product.

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 Chemo Ibérica

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

The usual dose of Telmisartan/Hydrochlorothiazide Chemo Ibérica is one tablet a day. Try to take the tablet at the same time each day. You can take Telmisartan/Hydrochlorothiazide Chemo Ibérica 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 Chemo Ibérica 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 Chemo Ibérica 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 drugs 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 Chemo Ibérica

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, Telmisartan/Hydrochlorothiazide Chemo Ibérica 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 in in 1,000 people) or of unknown frequency (toxic epidermal necrolysis) but are extremely serious and patients should stop taking the product 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 can not be ruled out for Telmisartan/Hydrochlorothiazide Chemo Ibérica.

Possible side effects of Telmisartan/Hydrochlorothiazide Chemo Ibérica:

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

Dizziness

Uncommon side effects (may affect 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 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 with Telmisartan/Hydrochlorothiazide Chemo Ibérica, 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 to 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 to 1,000 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 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, 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, skin and lip cancer (non-melanoma skin cancer), 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 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), 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.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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 IMB Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.imb.ie; e-mail: imbpharmacovigilance@imb.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Telmisartan/Hydrochlorothiazide Chemo Ibérica

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.

.You should store your medicine in the original (sealed) package in order to protect the tablets from moisture and light.

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 Chemo Ibérica contains

The active substances are telmisartan and hydrochlorothiazide. Each tablet contains 80 mg telmisartan and 25 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 (Hydroxipropylmethylcellulose) (E464), Carboxymethyl starch sodium from potato starch Type A Ferric Oxide Yellow (10E 172).

What Telmisartan/Hydrochlorothiazide Chemo Ibérica looks like and contents of the pack

Telmisartan/Hydrochlorothiazide Chemo Ibérica 80 mg/25 mg tablets are round bilayer tablets with white and yellow color. Telmisartan/Hydrochlorothiazide Chemo Ibérica is available in blisters packs containing 7, 10, 14, 28, 28x1, 30, 30x1m 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
Laboratorios Liconsa S.A.
C/ Dulcinea S/N,
28805 Alcalá de Henares, Madrid
Spain

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 EEA under the following names:
The Netherlands: Telmisartan/Hydrocloorthiazide Chemo Ibérica 80/25 mg tabletten
Austria Telmisartan/HCT +pharma 80 mg/25 mg Tabletten
Belgium: Telmisartan/Hydrochlorothiazide Chemo Ibérica 80/25 mg comprimés
Bulgaria: Telmisartan/Hydrochlorothiazide Chemo Ibérica 80/25 mg tablets
Luxemburg: Telmisartan/Hydrochlorothiazide Chemo Ibérica 80/25 mg tablets
Germany: Telmisartan/Hydrochlorothiazide AXiromed 80/25 mg tablets
Spain: Telmisartán / Hidroclorotiazida Stada 80/25 mg comprimidos EFG
France: Telmisartan/Hydrochlorothiazide Chemo Ibérica 80/25 mg tablets
Ireland: Telmisartan/Hydrochlorothiazide Chemo Ibérica 80/25 mg tablets
Portugal: Telmisartan/Hydrochlorothiazide Chemo Ibérica 80/25 mg comprimidos

This leaflet was last revised in 06/2021