Package leaflet: Information for the user

Mirpresoc 20 mg tablets
Mirpresoc 40 mg tablets
Mirpresoc 80 mg tablets
Telmisartan

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 Mirpresoc is and what it is used for

Mirpresoc belongs to a class of medicines known as 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. Mirpresoc blocks the effect of angiotensin II so that the blood vessels relax, and your blood pressure is lowered.

Mirpresoc is used to treat essential hypertension (high blood pressure) in adults. 'Essential' means that the high blood pressure is not caused by any other condition.

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.

Mirpresoc is also used to reduce cardiovascular events (i.e. heart attack or stroke) in adults who are at risk because they have a reduced or blocked blood supply to the heart or legs, or have had a stroke or have high risk diabetes. Your doctor can tell you if you are at high risk for such events.

2. What you need to know before you take Mirpresoc

Do not take Mirpresoc
- if you are allergic to telmisartan or any other ingredients of this medicine (listed in section 6).
- if you are more than 3 months pregnant. (It is also better to avoid Mirpresoc 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 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 Mirpresoc.

Warnings and precautions
Talk to your doctor if you are suffering or have ever suffered from any of the following conditions or illnesses:

• Kidney disease or kidney transplant.
• Renal artery stenosis (narrowing of the blood vessels to one or both kidneys).
• Liver disease.
• Heart trouble.
• Raised aldosterone levels (water and salt retention in the body along with imbalance of various blood minerals).
• 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, or vomiting.
• Elevated potassium levels in your blood.
• Diabetes.

Talk to your doctor before taking Mirpresoc

- 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 Mirpresoc"

- if you are taking digoxin.

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

In case of surgery or anaesthesia, you should tell your doctor that you are taking Mirpresoc.

Mirpresoc may be less effective in lowering the blood pressure in black patients.

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

Other medicines and Mirpresoc

Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines. Your doctor may need to change thedose of those other medicines /or take other precautions. In some cases you may have to stop taking one of the medicines. This applies especially to the medicines listed below taken at the same time with Mirpresoc:

- Lithium containing medicines to treat some types of depression.
- Medicines that may increase blood potassium levels such as salt substitutes containing potassium, potassium-sparing diuretics (certain 'water tablets'), ACE inhibitors, angiotensin II receptor antagonists, NSAIDs (non steroidal anti-inflammatory medicines, e.g. aspirin or ibuprofen), heparin, immunosuppressives (e.g. cyclosporin or tacrolimus), and the antibiotic trimethoprim.
- Diuretics ('water tablets'), especially if taken in high doses together with Mirpresoc, may lead to excessive loss of body water and low blood pressure (hypotension).
- If you are taking an ACE-inhibitor or aliskiren (see also information under the headings “Do not take Mirpresoc” and “Warnings and precautions”).
- Digoxin

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

Mirpresoc 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 Mirpresoc.

Mirpresoc with food and drink
You can take Mirpresoc with or without food.

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 Mirpresocbefore you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Mirpresoc. Mirpresoc. 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. Mirpresoc is not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breast-feed, especially if your baby is newborn, or was born prematurely.

Driving and using machines
Some people feel dizzy or tired when taking Mirpresoc. If you feel dizzy or tired, do not drive or operate machinery.

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

The recommended dose of Mirpresoc is one tablet a day. Try to take the tablet at the same time each day. You can take Mirpresoc with or without food. The tablets should be swallowed with some water or other non-alcoholic drink. It is important that you take Mirpresoc every day until your doctor tells you otherwise. If you have the impression that the effect of Mirpresoc is too strong or too weak, talk to your doctor or pharmacist.

For treatment of high blood pressure, the usual dose of Mirpresoc for most patients is one 40 mg tablet once a day to control blood pressure over the 24-hour period. However, sometimes your doctor may recommend a lower dose of 20 mg or a higher dose of 80 mg. Alternatively, Mirpresoc may be used in combination with diuretics ('water tablets') such as hydrochlorothiazide which has been shown to have an additive blood pressure lowering effect with Mirpresoc.
For reduction of cardiovascular events, the usual dose of Mirpresoc is one 80 mg tablet once a day. At the beginning of the preventive therapy with Mirpresoc 80 mg, blood pressure should be frequently monitored.

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

If you take more Mirpresoc than you should
If you accidentally take too many tablets, contact your doctor, pharmacist, or your nearest hospital emergency department immediately.

If you forget to take Mirpresoc
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 any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Some side effects can be serious and need immediate medical attention:

You should see your doctor immediately if you experience any of the following symptoms:

Sepsis* (often called "blood poisoning", is a severe infection with whole-body inflammatory response), rapid swelling of the skin and mucosa (angioedema); these side effects are rare (may affect up to 1 in 1,000 people) but are extremely serious and patients should stop taking the medicine and see their doctor immediately. If these effects are not treated they could be fatal.

Possible side effects of Mirpresoc:

Common side effects (may affect up to 1 in 10 people):
Low blood pressure (hypotension) in users treated for reduction of cardiovascular events.

Uncommon side effects (may affect up to 1 in 100 people):
Urinary tract infections,upper respiratory tract infections (e.g. sore throat, inflamed sinuses, common cold), deficiency in red blood cells (anaemia), high potassium levels, difficulty falling asleep, feeling sad (depression), fainting (syncope), feeling of spinning (vertigo), slow heart rate (bradycardia), low blood pressure (hypotension) in users treated for high blood pressure, dizziness on standing up (orthostatic hypotension), shortness of breath, cough, abdominal pain, diarrhoea, discomfort in the abdomen, bloating, vomiting, itching, increased sweating, drug rash, back pain, muscle cramps, muscle pain (myalgia), kidney impairment including acute kidney failure, pain in the chest, feeling of weakness, and increased level of creatinine in the blood.

Rare side effects (may affect up to 1 in 1,000 people):
Sepsis* (often called "blood poisoning", is a severe infection with whole-body inflammatory response which can lead to death), increase in certain white blood cells (eosinophilia),low platelet count (thrombocytopenia), severe allergic reaction (anaphylactic reaction), allergic reaction (e.g. rash, itching, difficulty breathing, wheezing, swelling of the face or low blood pressure), low blood sugar levels (in diabetic patients), feeling anxious, somnolence, impaired vision, fast heart beat (tachycardia), dry mouth, upset stomach, taste disturbance (dysgeusia), abnormal liver function (Japanese patients are more likely to experience this side effect), rapid swelling of the skin and mucosa which can also lead to death (angioedema also with fatal outcome), eczema (a skin disorder),redness of skin, hives (urticaria), severe drug rash, joint pain (arthralgia), pain in extremity, tendon pain, flu-like-illness, decreased haemoglobin (a blood protein), increased levels of uric acid, increased hepatic enzymes or creatine phosphokinase in the blood.

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.

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, 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 Mirpresoc

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 and blister after “EXP”. The expiry date refers to the last day of that month.

Aluminium/aluminium blisters: This medicinal product does not require any special storage conditions.

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 Mirpresoc contains
• The active substance is telmisartan: a tablet of 20 mg of Mirpresoc contains 20 mg of Telmisartan; a tablet of 40 mg of Mirpresoc contains 40 mg of Telmisartan; a tablet of 80 mg of Mirpresoc contains 80 mg of Telmisartan
• The other ingredients are povidone (K25) (E1201), meglumine, sodium hydroxide (E524), mannitol (E421), crospovidone (E1202) and magnesium stearate (E470b).

What Mirpresoc looks like and contents of the pack
Mirpresoc are tablets.
Mirpresoc 20 mg: are white, round bevelled tablets with LC debossed on one side.
Mirpresoc 40 mg: are white, oblong tablets with LC debossed on one side.
Mirpresoc 80 mg: are white, oblong tablets with LC debossed on one side.

Mirpresoc is provided in blisters containing 14, 28, 30, 56, 84, 90 or 98 tablets.

Not all pack sizes or tablet strengths may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
Laboratorios Liconsa S.A.
C/Dulcinea S/N , Alcalá de Henares
28805, Madrid, Espanha

Manufacturer:
Laboratorios Liconsa, S.A.
Avda. Miralcampo, Nº 7, Polígono Industrial Miralcampo
19200 Azuqueca de Henares (Guadalajara), Spain

HEUMANN PHARMA
GmbH & Co. Generica KG
Südwestpark 50 · 90449 Nürnberg

This medicinal product is authorised in the Member States of the EEA under the following names:

Name of the Member States	Name of the medicinal product
Portugal	Mirpresoc 20 mg, 40 mg and 80 mg Comprimidos
Ireland	Mirpresoc 20 mg, 40 mg and 80 mg tablets
Germany	Telmisartan Heumann 20 mg, 40mg , 80 mg Tabletten
Spain	Telmisartán STADA 20 mg, 40 mg, 80 mg comprimidos EFG

This leaflet was last revised in:
[To be completed nationally]