PACKAGE LEAFLET: INFORMATION FOR THE USER

<invented name> 20 mg tablets
<invented name> 40 mg tablets
<invented name> 80 mg tablets
Telmisartan

Read all of this leaflet carefully before you start taking this medicine.
- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. WHAT <invented name> 20/40/80 mg tablets ARE AND WHAT THEY ARE USED FOR

<invented name> 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. <invented name> blocks the effect of angiotensin II so that the blood vessels relax, and your blood pressure is lowered.

<invented name> is used to treat essential hypertension (high blood pressure). '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.

<invented name> is also used to reduce cardiovascular events (i.e. heart attack or stroke) in patients 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 event.

2. BEFORE YOU TAKE <INVENTED NAME> 20/40/80 mg tablets

Do not take <invented name>
• if you are allergic (hypersensitive) to telmisartan or any other ingredients included in <invented name> tablets (see section Further information for a list of other ingredients).

• if you are more than 3 months pregnant. (It is also better to avoid <invented name> in early pregnancy – see pregnancy section

• if you have severe liver problems such as cholestasis or biliary obstruction (problems with the drainage of the bile from the liver and gall bladder) or any other severe liver disease.

If any of the above applies to you, tell your doctor or pharmacist before taking <invented name>.

Take special care with <invented name>
Please tell 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.

You must tell your doctor if you think that you are (or might become) pregnant. <invented name> 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 bay if uses at that stage (see pregnancy section)

In case of surgery or anaesthesia, you should tell your doctor that you are taking <invented name>.

The use of <invented name> in children and adolescents up to the age of 18 years is not recommended.

As with all other angiotensin II receptor antagonists, <invented name> may be less effective in lowering the blood pressure in black patients.

Taking other medicines
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Your doctor may need to change the dose of these other medicines or take other precautions. In some cases you may have to stop taking one of the medicines. This applies especially to the medicines listed below taken at the same time with <invented name>:

• 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 <invented name>, may lead to excessive loss of body water and low blood pressure (hypotension).

As with other blood pressure lowering medicines, the effect of <invented name> may be reduced when you take NSAIDs (non steroidal anti-inflammatory medicines, e.g. aspirin or ibuprofen) or corticosteroids.

<invented name> may increase the blood pressure lowering effect of other medicines used to treat high blood pressure.

Taking <invented name> with food and drink
You can take <invented name> with or without food.

Pregnancy and breast-feeding
Pregnancy
You must tell your doctor if you think that you are (or might become) pregnant. Your doctor will normally advise you to stop taking <invented name>before you become pregnant or as soon as you are pregnant and will advise you to take another medicine instead of <invented name>. <invented name>. is not recommended in early pregnancy, and must not be taken when more that 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. <invented name> is not recommended for mother 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
No information is available on the effect of <invented name> on the ability to drive or operate machinery.
Some people feel dizzy or tired when they are treated for high blood pressure. If you feel dizzy or tired, do not drive or operate machinery.

3. HOW TO TAKE <INVENTED NAME> 20/40/80 mg tablets

Always take <invented name> exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

To obtain the tablet follow the steps:

1.- Separate one individual blister cell from the rest of the strip by gently tearing along the perforations.
2.- Carefully peel off the backing
3.- Push the tablet out.

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

For treatment of high blood pressure, the usual dose of <invented name> for most patients is one 40 mg tablet once a day to control blood pressure over the 24-hour period. <invented name> may also be used in combination with diuretics ('water tablets') such as hydrochlorothiazide which has been shown to have an additive blood pressure lowering effect with <invented name>.

For reduction of cardiovascular events, the usual dose of <invented name>is one 80 mg tablet once a day. At the beginning of the preventive therapy with <invented name>, 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 <invented name> 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 <invented name>
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 product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, <invented name> can cause side effects, although not everybody gets them. These side effects may occur with certain frequencies, which are defined as follows:

- very common: affects more than 1 user in 10
- common: affects 1 to 10 users in 100
- uncommon: affects 1 to 10 users in 1,000
- rare: affects 1 to 10 users in 10,000
- very rare: affects less than 1 user in 10,000
- not known: frequency cannot be estimated from the available data.

Common side effects may include:
Low blood pressure (hypotension) in users treated for reduction of cardiovascular events.

Uncommon side effects may include:
Upper respiratory tract infection (e.g. sore throat, inflamed sinuses, common cold), urinary tract infections, deficiency in red blood cells (anaemia),high potassium levels, feeling sad (depression) fainting (syncope), difficulty falling asleep, 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, abdominal pain, diarrhoea, discomfort in the abdomen, bloating, vomiting, increased sweating, itching, drug rash, muscle pain (myalgia), back pain, kidney impairment including acute kidney failure, and pain in the chest, feeling of weakness, and increased level of creatinine in the blood

Rare side effects may include:
Low platelet count (thrombocytopenia), allergic reaction (e.g. rash, itching, difficulty breathing, wheezing, swelling of the face or low blood pressured), feeling anxious, impaired vision, fast heart beat (tachycardia), upset stomach, dry mouth, , abnormal liver function, severe drug rash,redness of skin, rapid swelling of the skin and mucosa (angioedema), eczema (a skin disorder) joint pain (arthralgia), , , pain in extremity, symptoms of weakness, flu-like-illness, increased levels of uric acid, creatinine, hepatic enzymes or creatine phosphokinase in the blood, and decreased haemoglobin (a blood protein)

Side effects of unknown frequency may include:
Increase in certain white blood cells (eosinophilia), severe allergic reaction (e.g. rash, itching, difficulty breathing, wheezing, swelling of the face or low blood pressure), hives (urticaria), inflammation of the tendons, and sepsis* (often called "blood poisoning", is a severe infection with whole body inflammatory response which can lead to death)

*In a long term-study involving more than 20,000 patients, more patients with telmisartan experienced sepsis compared with patients who received no telmisartan. The event may have happened by chance or could be related to a mechanism not know.

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

5. HOW TO STORE <invented name> 20/40/80 mg tablets

Keep out of the reach and sight of children.

Do not use <invented name> 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.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What <invented name> contains
• The active substance is telmisartan: a tablet of 20 mg of <invented name> contains 20 mg of Telmisartan; a tablet of 40 mg of <invented name> contains 40 mg of Telmisartan; a tablet of 80 mg of <invented name> contains 80 mg of Telmisartan
• The other ingredients are povidone, meglumine, sodium hydroxide, mannitol, crospovidone and magnesium stearate.

What <invented name> looks like and contents of the pack
<invented name> are tablets.
<invented name> 20 mg: are white, round bevelled tablets.
<invented name> 40 mg: are white or slightly yellowish, oblong tablets.
<invented name> 80 mg: are white or slightly yellowish, oblong tablets.

[PT/H/264-265-266-268/001-003/DC]
<invented name> is provided in blisters containing 14, 28, 30, 56, 84, 90 or 98 tablets.

[PT/H/267-280-281-282/001-003/DC]
<invented name> is provided in blisters containing 28 tablets.

Not all pack sizes or tablet strengths may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
[To be completed nationally]

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

PharmaSwiss d.o.o.,
Wolfova 1,
SI-1000 Ljubljana,
Slovenia

ICN Polfa Rzeszów S.A.
2 Przemysłowa Street
35-959 Rzeszów
Poland

Valeant sp. z o.o. sp. j.
ul. Przemysłowa 2
35-959 Rzeszów
Poland

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

[PT/H/264/001-003/DC]
Portugal, Austria:, Belgium, Czech Republic, Germany, Denmark, Spain, France, , Ireland, Luxembourg, The Nederlands, Poland, Slovenia, Slovac Republic, United Kingdom:
Zanacodar 20, 40 and 80 mg tablets

[PT/H/265/001-003/DC]
Portugal, Austria, Belgium, Czech Republic, Germany, Spain, Finland, France, Ireland, The Nederlands, Poland, Slovenia, Slovac Republic, United Kingdom:
Dinortes 20, 40 and 80 mg tablets

[PT/H/266/001-003/DC]
Portugal, Austria, Belgium, Czech Republic, Germany, Spain, France, Ireland, The Nederlands, Poland, Slovenia, Slovac Republic, United Kingdom:
Tengradoc 20, 40 and 80 mg tablets

[PT/H/267/001-003/DC]
Portugal, Italy:
Meldoc 20, 40 and 80 mg tablets

[PT/H/268/001-003/DC]
Portugal, Bulgary, Greece:
Tesgreco 20, 40 and 80 mg tablets

[PT/H/280/001-003/DC]
Portugal, Italy:
Terdefel 20, 40 and 80 mg tablets

[PT/H/281/001-003/DC]
Portugal, Italy:
Diterpris 20, 40 and 80 mg tablets

[PT/H/282/001-003/DC]
Portugal, Italy:
Siterbon 20, 40 and 80 mg tablets

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