Package leaflet: Information for the user

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

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

1. What Telmisartan is and what it is used for

Telmisartan belongs to a class of medicines known as angiotensin II receptor blockers. Angiotensin II is a substance produced in your body which causes your blood vessels to narrow, thus increasing your blood pressure. Telmisartan blocks the effect of angiotensin II so that the blood vessels relax, and your blood pressure is lowered.

Telmisartan 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.

Telmisartan 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 Telmisartan

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

Warnings and precautions
Talk to your doctor before taking Telmisartan 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 e.g. diuretic therapy ('water tablets'), low-salt diet, diarrhoea, or vomiting.
- Elevated potassium levels in your blood.
- Diabetes.

Talk to your doctor before taking Telmisartan:
- 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".
- if you are taking digoxin.

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

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

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

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

Other medicines and Telmisartan
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Your doctor may need to change the dose of these other medications or take other precautions. In some cases you may have to stop taking one of the medicines. This applies especially to the medicines listed below taken at the same time with Telmisartan:
- 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 blockers, 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 Telmisartan, 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 Telmisartan" and "Warnings and precautions").
- Digoxin.

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

Telmisartan 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.

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 before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Telmisartan. Telmisartan 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 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 may experience side effects such as fainting or a feeling of spinning (vertigo) when taking Telmisartan. If you experience these side effects, do not drive or operate machinery.

Telmisartan contains sodium
This medicine contains less than 1 mmol sodium (23 mg) each tablet, that is to say essentially 'sodium-free'.

3. How to take Telmisartan

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

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

For treatment of high blood pressure, the usual dose of Telmisartan 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, Telmisartan 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 Telmisartan.

For reduction of cardiovascular events, the usual dose of Telmisartan is one 80 mg tablet once a day. At the beginning of the preventive therapy with Telmisartan 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 Telmisartan 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 Telmisartan
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 Telmisartan
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), dizziness, 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, pain in the belly, 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, discomfort in the belly, 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 including 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, low levels of sodium.

Very rare side effects (may affect up to 1 in 10 000 people):
Progressive scarring of lung tissue (interstitial lung disease)**.

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

* The event may have happened by chance or could be related to a mechanism currently not known.

** Cases of progressive scarring of lung tissue have been reported during intake of telmisartan. However, it is not known whether telmisartan was the cause.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via
HPRA Pharmacovigilance
Website: www.hpra.ie
By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Telmisartan

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

This medicinal product does not require any special temperature storage conditions.
Store in the original package in order to protect from moisture.

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 contains
The active substance is telmisartan.
Each tablet contains 20 mg, 40 mg or 80 mg telmisartan.

The other ingredients are: mannitol, sodium hydroxide, meglumine and magnesium stearate

What Telmisartan looks like and contents of the pack
Telmisartan 20 mg tablets
White to off white, approximately 7.1 mm, round, flat, bevel edged, tablets, debossed with ‘H’ on one side and ‘162’ on the other side.

Telmisartan 40 mg tablets
White to off white, approximately 12.1 x 5.9 mm, oval shaped, biconvex, tablets, debossed with ‘H’ on one side and ‘163’ on the other side.

Telmisartan 80 mg tablets
White to off white, approximately 16.3 x 8.0 mm, oval shaped, biconvex, tablets, debossed with ‘H’ on one side and ‘164’ on the other side.

Telmisartan is available in blisters containing
20 mg: 28, 30 and 98 tablets.
40 mg: 28, 56, 98 and 100 tablets.
80 mg: 28, 56, 98 and 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Amarox Pharma B.V.

Rouboslaan 32
2252 TR Voorschoten
Netherlands.

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

BG	Телмисартан Amarox 20 mg/40 mg/80 mg таблетки
CZ	Telmisartan Amarox
DE	Telmisartan Amarox 20 mg/40 mg/80 mg Tabletten
EE	Telmisartaan Amarox
ES	Telmisartán Tarbis 20 mg/40 mg/80 mg comprimidos EFG
FI	Telmisartan Amarox 20 mg/40 mg/80 mg tabletit
FR	TELMISARTAN AMAROX 20 mg/40 mg/80 mg, comprimé
HU	Telmizartán Amarox 20 mg/40 mg/80 mg tabletta
IE	Telmisartan 20 mg/40 mg/80 mg tablets
IT	Telmisartan Amarox
NL	Telmisartan Amarox 20 mg/40 mg/80 mg tabletten
PL	Telmisartan Amarox
RO	Telmisartan Amarox 20 mg/40 mg/80 mg comprimate
SE	Telmisartan Amarox 20 mg/40 mg/80 mg tabletter
SK	Telmisartan Amarox 20 mg/40 mg/80 mg tablety

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