Package leaflet: Information for the patient

Telmisartan Mylan 20 mg tablets
Telmisartan Mylan 40 mg tablets
Telmisartan Mylan 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 Telmisartan Mylan is and what it is used for

Telmisartan Mylan contains telmisartan, which 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 which increases your blood pressure. Telmisartan Mylan blocks the effect of angiotensin II so that the blood vessels relax, and your blood pressure is lowered.

Telmisartan Mylan 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.

If high blood pressure is not treated it can damage blood vessels in some organs, which could possibly lead 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 Mylan is also used to reduce the risk of heart attack or stroke in adults who are at risk because they have a reduced or blocked blood supply to the heart or legs, have had a stroke in the past or already have organ damage caused by 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 Mylan

Do not take Telmisartan Mylan
- 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 Mylan 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 you have diabetes mellitus 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 Mylan**.**

Warnings and precautions

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

- if you have kidney disease or have had a kidney transplant
- if you have narrowing of the blood vessels to one or both kidneys (renal artery stenosis)
- if you have any other liver disease
- if you suffer from heart trouble
- if you have low blood pressure (hypotension), likely to occur if you have an excessive loss of body water (dehydration), have low salt levels because you are taking 'water tablets' or are on a low-salt diet or you have diarrhoea or vomiting
- if you have water and salt retention in the body along with imbalance of various blood minerals (raised aldosterone levels)
- if you have high elevated potassium levels in your blood
- if you have diabetes

Talk to your doctor or pharmacist before taking Telmisartan Mylan:

- if you are taking digoxin
- 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 Mylan"

If you are black, as with all other angiotensin II receptor antagonists, Telmisartan Mylan may be less effective in lowering the blood pressure in black patients.

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

If you are having surgery or an anaesthetic, you should tell your doctor that you are taking Telmisartan Mylan.

Children and adolescents

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

Other medicines and Telmisartan Mylan

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Your doctor may need to change your dose of these other medicines and/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 Mylan:

- Lithium (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. ciclosporin or tacrolimus), and the antibiotic trimethoprim.
- 'Water tablets' (diuretics) e.g. furosemide, hydrochlorothiazide, amiloride; especially if taken in high doses together with Telmisartan Mylan, may lead to excessive loss of body water and low blood pressure (hypotension).
- As with other blood pressure lowering medicines, the effect of Telmisartan Mylan may be reduced when you take NSAIDs (non-steroidal anti-inflammatory medicines, e.g. aspirin or ibuprofen) or corticosteroids
- Other medicines to treat high blood pressure, strong pain killers, barbiturates (for epilepsy), baclofen (used to treat cerebral palsy and multiple sclerosis), amifostine (used to prevent fever and infections in patients receiving chemotherapy or radiotherapy) or tablets for depression

- If you are taking an ACE-inhibitor or aliskiren (see also information under the headings "Do not take Telmisartan Mylan" and "Warnings and precautions")
- Digoxin

Telmisartan Mylan may increase the blood pressure lowering effect of other medicines used to treat high blood pressure.

Telmisartan Mylan with alcohol

Telmisartan Mylan may increase the blood pressure lowering effect if taken with alcohol, which may make you feel dizzy or lightheaded and faint, especially when standing after you have been sitting or lying down.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

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. 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 taken 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 new born, or was born prematurely.

Driving and using machines

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.

Telmisartan Mylan contains sodium

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

3. How to take Telmisartan Mylan

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

The recommended dose of Telmisartan Mylan will depend on what you are taking this medicine for. You should take your dose once a day and at the same time each day.

For the treatment of high blood pressure, the recommended dose is 40 mg once a day to control high 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. 20 mg may be a high enough dose for some patients. Telmisartan Mylan may also be used with diuretics ("water tablets") such as hydrochlorothiazide which has been shown to have an additive blood pressure lowering effect with telmisartan.

To reduce the risk of a heart attack or stroke the recommended dose is 80 mg daily. At the beginning of treatment your blood pressure should be frequently monitored.

If you have the impression that the effect of Telmisartan Mylan is too strong or too weak, talk to your doctor or pharmacist.

Your medicine is available in 3 strengths:
20 mg, 40 mg and 80 mg

Use in children and adolescents

Children and adolescents under 18 years old should not take Telmisartan Mylan.

Method of administration

Swallow the tablets whole with water or other non-alcoholic drink.

You can take Telmisartan Mylan with or without food.

Patients with liver problems
If your liver is not working properly, the recommended dose should not be higher than 40 mg once daily.

Patients with kidney problems

If you have kidney problems, please discuss this with your doctor. Your doctor may prescribe you a lower starting dose of 20 mg daily.

If you take more Telmisartan Mylan than you should

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

Signs to look for are low blood pressure, dizziness, increase or decrease in heart beat and kidney problems.

If you forget to take Telmisartan Mylan

If you forget to take your tablets do not worry. Take them 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 a forgotten dose.

If you stop taking Telmisartan Mylan

If you want to stop taking this medicine talk to your doctor.

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 as they could be fatal if not treated:

- Sepsis* (often called "blood poisoning", is a severe infection with whole-body inflammatory response)
- Severe allergic reaction with symptoms such as rash, itching, difficulty breathing, wheezing, swelling of the face or low blood pressure (anaphylactic reaction)
- Rapid swelling of the skin, face, lips, mouth tongue or throat, which can cause difficulty in swallowing or breathing (angioedema).
- Severe skin reactions, which may include blisters and peeling of the skin (toxic skin reaction)
- Problems passing water with tiredness, feeling and being sick, breathlessness and swelling of legs, ankles or feet (Kidney impairment including kidney failure)
- Shortness of breath with a dry or non-productive cough with weight loss, due to progressive scarring of lung tissue (interstitial lung disease) ***

Other possible side effects:

Common (may affect up to 1 in 10 people):

- Low blood pressure (hypotension) in users treated for reduction of cardiovascular events e.g.heart attack or strokes

Uncommon (may affect up to 1 in 100 people):

- Upper respiratory tract infection (e.g. sore throat, common cold, inflamed and swollen sinuses causing pain, high temperature and tenderness)
- Urinary tract infection including inflammation of the bladder lining
- Deficiency in red blood cells (anaemia), which can make the skin pale and cause weakness and breathlessness
- High potassium levels, which show up in blood tests
- Feeling sad (depression)
- Difficulty falling asleep
- Feeling of spinning (vertigo)
- Fainting (syncope)
- Dizziness or light-headedness, especially when standing up (orthostatic hypotension)
- Slower heart beat (bradycardia)

- Low blood pressure (hypotension) in users treated for high blood pressure.
- Shortness of breath and chest pain
- Cough
- Stomach pain, diarrhoea, indigestion, bloating or vomiting
- Rash, itchy skin
- Increased sweating
- Back pain, muscle pain (myalgia), muscle spasms
- Weakness
- Increase in level of a substance called creatinine in the blood, which shows up in blood tests

Rare (may affect up to 1 in 1,000 people):
- Reduction in blood platelets which increase risk of bleeding or bruising
- Increase in certain white blood cells (eosinophilia), which shows up in blood tests
- Feeling anxious
- Visual disturbance (impaired vision)
- Faster heart beat (tachycardia)
- Dry mouth
- Taste disturbance (dysgeusia)
- Abnormal liver function **
- Inflammation of the skin, marked by itching and rash and often including blisters (eczema), redness of skin, hives (urticaria)
- Joint pain (arthralgia), pain in extremity or tendon pain
- Flu like symptoms (influenza like illness)
- An increase in some blood enzyme levels (levels such as increased liver enzymes or creatine phosphokinase) which shows up in blood tests.
- Low blood sugar levels (in diabetic patients)
- Decreased haemoglobin (a blood protein), which shows up in blood tests.
- Increased level of uric acid, which shows up in blood tests.
- Sleepiness
- Stomach discomfort

*In a long-term study involving more than 20,000 patients, more patients treated 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 currently not known.

** Most cases of abnormal liver function and liver disorder from post-marketing experience with telmisartan occurred in Japanese patients. Japanese patients are more likely to experience this side effect

*** 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, pharmacist or nurse. 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 Mylan

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

Store in the original package in order to protect from light.

Do not use Telmisartan Mylan if you notice any discolouration of the tablets.

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 Mylan contains

- The active substance is telmisartan
- Each tablet contains 20 mg or 40 mg or 80 mg telmisartan
- The other ingredients are magnesium stearate, povidone, meglumine, sodium hydroxide and mannitol (E421)

What Telmisartan Mylan looks like and contents of the pack

20 mg: White to off white, round flat, bevelled edged tablets marked with 'TN over 20' on one side and 'M' on the other side.

40 mg: White to off white, oblong, tablets with sides that curve outwards marked with 'TN40' on one side and 'M' on the other side.

80 mg: White to off white, oblong, tablets with sides that curve outwards marked with 'TN80' on one side and 'M' on the other side.

Telmisartan Mylan is available in blister packs of 14, 28, 30, 56, 60, 84, 90, 98, 100 tablets and calendar pack size of 28 tablets, and plastic bottles with plastic cap containing an absorbent cotton and a desiccant container (do not eat the dessicant) in pack sizes of 56, 60, 84, 90, 98, 280, 500, 1000 tablets.
Telmisartan Mylan 80 mg tablets is also available in a blister multipack of 98 comprising of 2 cartons, each containing 49 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
McDermott Laboratories Ltd, t/a Gerard Laboratories
35/36 Baldoyle Industrial Estate,
Grange Road,
Dublin 13, Ireland

Manufacturers
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This medicinal product is authorised in the Member States of the EEA and in the United Kingdom (Northern Ireland) under the following names:

Belgium	Telmisartan Viatris 20 mg, 40 mg, 80 mg tabletten
France	TELMISARTAN VIATRIS 40 mg, 80 mg comprimé
Germany	Telmisartan Mylan 20 mg, 40 mg, 80 mg Tabletten
Ireland	Telmisartan Mylan 20 mg, 40 mg, 80 mg
Luxemburg	Telmisartan Viatris 20 mg, 40 mg, 80 mg CPR
Poland	Telmisartan Viatris
Portugal	Telmisartan Mylan
Spain	TELMISARTAN VIATRIS 20 mg, 40 mg, 80 mg COMPRIMIDOS EFG
The Netherlands	Telmisartan Viatris 20 mg, 40 mg, 80 mg tabletten
United Kingdom (Northern Ireland)	Telmisartan Mylan 20 mg, 40 mg, 80 mg Tablets

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