

Package leaflet: Information for the user

Telmisartan Clonmel 20 mg film-coated tablets

Telmisartan Clonmel 40 mg film-coated tablets

Telmisartan Clonmel 80 mg film-coated 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 or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Telmisartan Clonmel is and what it is used for

Telmisartan Clonmel 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. Telmisartan Clonmel blocks the effect of angiotensin II so that the blood vessels relax, and your blood pressure is lowered.

Telmisartan Clonmel 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.

Telmisartan Clonmel 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 events.

2. What you need to know before you take Telmisartan Clonmel

Do not take Telmisartan Clonmel

- 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 Clonmel 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 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 Clonmel.

Warnings and precautions

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.

Talk to your doctor, pharmacist or nurse before taking Telmisartan Clonmel

- 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 Clonmel”

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

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

Children and adolescents

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

As with all other angiotensin II receptor antagonists, Telmisartan Clonmel may be less effective in lowering the blood pressure in black patients.

Other medicines and Telmisartan Clonmel

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 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 Telmisartan Clonmel:

- 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. ciclosporin or tacrolimus), and the antibiotic trimethoprim.
- diuretics ('water tablets'), especially if taken in high doses together with Telmisartan Clonmel, 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 Clonmel” and “Warnings and precautions”).

As with other blood pressure lowering medicines, the effect of Telmisartan Clonmel may be reduced when you take NSAIDs (non steroidal anti-inflammatory medicines, e.g. aspirin or ibuprofen) or corticosteroids. Telmisartan Clonmel may increase the blood pressure lowering effect of other medicines used to treat high blood pressure.

Telmisartan Clonmel with food

You can take Telmisartan Clonmel with or without food.

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

Your doctor will normally advise you to stop taking Telmisartan Clonmel before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Telmisartan Clonmel. Telmisartan Clonmel 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

Telmisartan Clonmel 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

No information is available on the effect of Telmisartan Clonmel 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.

Telmisartan Clonmel contains lactose and sodium

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

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

3. How to take Telmisartan Clonmel

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

For the treatment of high blood pressure, the recommended dose of Telmisartan Clonmel 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. Telmisartan Clonmel may also be used in combination with diuretics ('water tablets').

For reduction of cardiovascular events, the recommended dose of Telmisartan Clonmel is one 80 mg tablet once a day. At the beginning of the preventive therapy with Telmisartan Clonmel 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 Clonmel 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 Clonmel

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 a forgotten dose.

If you stop taking Telmisartan Clonmel

Do not stop taking Telmisartan Clonmel without talking to your doctor.

Medicines for high blood pressure may need to be taken for the rest of your life. If you stop taking Telmisartan Clonmel your blood pressure will return to the level it was before treatment in a few days.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist or nurse.

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

- low blood pressure (hypotension) in users treated for reduction of cardiovascular events.

Uncommon (may affect up to 1 to 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)
- dizziness
- 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
- increased level of creatinine in the blood

Rare (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
- abnormal liver function (Japanese patients are more likely to experience these side effects), 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 (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.

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.

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 Clonmel

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.

This medicine 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 Telmisartan Clonmel contains

- The active substance is telmisartan, each tablet contains 20mg/40mg/80mg telmisartan.
- The other ingredients are:
 - Sodium hydroxide
 - Povidone (K-25)
 - Meglumine
 - Lactose monohydrate
 - Crospovidone
 - Ferric oxide yellow (E172)
 - Magnesium stearate

The film-coating contains:

Hypromellose
Titanium dioxide (E171)
Macrogol-400
Talc
Ferric oxide yellow (E172)

What Telmisartan Clonmel looks like and contents of the pack

Telmisartan Clonmel 20 mg are yellow, circular shaped film-coated tablets with ‘20’ engraved on one side and ‘T’ engraved on the other side.

Telmisartan Clonmel 40 mg are yellow, capsule shaped film-coated tablets with ‘40’ engraved on one side and ‘T’ engraved on the other side.

Telmisartan Clonmel 80 mg are yellow, capsule shaped film-coated tablets with ‘80’ engraved on one side and ‘T’ engraved on the other side.

Telmisartan Clonmel 20 mg is available in blister packs containing 7, 10, 14, 15, 28, 30, 56, 60, 84, 90, 98, 112, 126, 140, 154, 168 or 182 tablets.

Telmisartan Clonmel 40 mg is available in blister packs containing 7, 10, 14, 15, 28, 30, 50, 56, 60, 84, 90, 98, 112, 126, 140, 154, 168 or 182 tablets.

Telmisartan Clonmel 80 mg is available in blister packs containing 7, 10, 14, 15, 28, 30, 50, 56, 60, 84, 90, 98, 112, 126, 140, 154, 168 or 182 tablets.

Not all pack sizes may be marketed in your country.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

Manufacturer:

Glenmark Pharmaceuticals s.r.o., Fibichova 143, 566 17 Vysoké Mýto, Czech Republic

Tillomed Laboratories Ltd, 3 Howard Road, Eaton Socon, St. Neots, Cambridgeshire, PE 198ET, United Kingdom

STADA Arzneimittel AG, Stadastrasse 2-18, 61118 Bad Vilbel, Germany

STADA Arzneimittel GmbH, Muthgasse 36, 1190 Wien, Austria

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

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

United Kingdom	Telmisartan STADA 20mg, 40mg, 80mg film-coated tablets
Austria	Telmisartan STADA 20mg, 40mg, 80mg Filmtabletten
Belgium	Telmisartan EG 20mg, 40mg, 80mg filmomhulde tabletten
Bulgaria	Telmisartan STADA 20mg, 40mg, 80mg Филмирана таблетка
Denmark	Telmisartan STADA
Finland	Telmisartan STADA 20mg, 40mg, 80mg Tabletti, kalvopäällysteinen
France	Telmisartan EG 20mg, 40mg, 80mg Comprimés pelliculé
Germany	Telmisartan STADA 20mg, 40mg, 80mg Filmtabletten
Ireland	Telmisartan Clonmel 20mg, 40mg, 80mg film-coated tablets
Luxembourg	Telmisartan EG 20mg, 40mg, 80mg comprimés pelliculé
Portugal	Telmisartan Ciclum
Spain	Telmisartán STADA 20mg, 40mg, 80mg Comprimido recubierto con película EFG
Sweden	Telmisartan STADA 20mg, 40mg, 80mg Filmdragerad tablett
Italy	Telmisartan EG 20mg, 40mg, 80mg Compresa rivestita con film
Netherlands	Telmisartan CF 20mg, 40mg, 80mg Filmomhulde tabletten

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