

Telmizal®

Telmizal tablets 20 mg

Telmizal tablets 40 mg

Telmizal tablets 80 mg

(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 **Telmizal** is and what it is used for.
2. What you need to know before you take **Telmizal**.
3. How to take **Telmizal**.
4. Possible side effects.
5. How to store **Telmizal**.
6. Further information.

1. What Telmizal is and what it is used for

- **Telmizal** 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.

- **Telmizal** blocks the effect of angiotensin II so that the blood vessels relax, and your blood pressure is lowered.

- **Telmizal** 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.

- **Telmizal** 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 Telmizal Do not take this medicine:

- 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 this medicine in early pregnancy—see pregnancy section.)
- if you have severe liver problems such as cholestasis or biliary obstruction 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 this medicine

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, low-salt diet, diarrhoea, or vomiting.
- Elevated potassium levels in your blood.
- Diabetes.

Talk to your doctor before taking this medicine:

- 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 this medicine".
- if you are taking digoxin.

You must tell your doctor if you think you are (or might become) pregnant. **Telmizal** 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 this medicine. Telmisartan may be less effective in lowering the blood pressure in black patients.

Children and adolescents

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

Taking other medicines

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 **Telmizal** :

- 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, 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, especially if taken in high doses together with **Telmizal**, 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 this medicine" and "Warning and precautions").
- Digoxin.

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

Telmizal 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 **Telmizal** .

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 **Telmizal** before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of **Telmizal**.

Telmizal 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. **Telmizal** 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 **Telmizal**. If you feel dizzy or tired, do not drive or operate machinery.

3. How to take Telmizal

- 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 **Telmizal** is one tablet a day. Try to take the tablet at the same time each day.

- You can take this medicine with or without food. The tablet should be swallowed with some water or other non-alcoholic drink. It is important that you take this medicine every day until your doctor tells you otherwise. If you have the impression that the effect of this medicine is too strong or too weak, talk to your doctor or pharmacist.

- For treatment of high blood pressure, the usual dose of this medicine for most patients is one 40 mg tablet once a day to control blood pressure over the 24 hour period. Your doctor can recommend a lower dose of one 20 mg tablet daily. This medicine may also be used in combination with diuretics such as hydrochlorothiazide which has been shown to have an additive blood pressure lowering effect with this medicine.

-For reduction of cardiovascular events, the usual dose of **Telmizal** is one 80 mg tablet once a day. At the beginning of the preventive therapy with **Telmizal** 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 of this medicine than you should

If you take more of this medicine than you should, talk to a doctor or your nearest hospital emergency department immediately.

If you forget to take Telmizal

If you forget to take a dose, just take your next dose as normal. 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 have any further questions on the use of this medicine, ask your doctor, 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 Telmizal:

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 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 (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 these 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 creatinine 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.

5. How to store this medicine

• Keep this medicine out of the sight and reach of children.

• Keep this medicine in dry place and temperature not exceed 30°C. Store in the original package in order to protect from moisture.

• Do not use this medicine after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

• 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. Further information

What this medicine contains

• The active substance is telmisartan. Each film-coated tablet contains 20 mg, 40 mg or 80 mg of Telmisartan.

• The other ingredients are mannitol, povidone, meglumine, sodium hydroxide, magnesium stearate.

What this medicine looks like and contents of the pack

• **Telmizal** 20 mg Tablets are white and round shaped. They are supplied in packs containing 3 blisters, each blister contains 10 tablets.

• **Telmizal** 40 mg Tablets are white and round shaped. They are supplied in packs containing 3 blisters, each blister contains 10 tablets.

• **Telmizal** 80 mg Tablets are white and oblong. They are supplied in packs containing 3 blisters, each blister contains 10 tablets.

Marketing Authorization holder and manufacturer:

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To report any Side effect

National Medicines and Poisons Board (NMPB)
Fax (+249)185322263
E-mail: info@nmpb.gov.sd
Website: www.nmpb.gov.sd

THIS IS A MEDICAMENT

- Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consultation your doctor.
- Keep medicament out of reach of children.

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Khartoum - Sudan

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