

NOUMED TELMISARTAN

telmisartan tablets

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about NOUMED TELMISARTAN.

It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of taking this medicine against the benefits it is expected to have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What NOUMED TELMISARTAN is used for

NOUMED TELMISARTAN tablets contain the active ingredient telmisartan, which belongs to a group of medicines called angiotensin II receptor antagonists or blockers ('sartans' or ARBs) that help relax blood vessels.

It is used to:

- lower high blood pressure (also called hypertension),
- prevent cardiovascular complications (including death) in elderly patients 55 years or older with certain related conditions.

Hypertension

Everyone alive has blood pressure. As your heart contracts and relaxes to pump blood into the arteries providing needed oxygen and nutrients around your body, the pressure goes from high (systolic) to low (diastolic) with each heartbeat.

Your blood pressure may vary at different times of the day, depending on how busy, worried or relaxed you are. It may also change as you grow older, and the condition of your heart, arteries and health changes.

There are usually no signs of hypertension. After regularly checking your blood pressure, your doctor may diagnose hypertension if your blood pressure stays higher than normal, even when you are calm or relaxed.

Uncontrolled hypertension can lead to serious health problems, including stroke, heart disease and kidney failure. Telmisartan helps lower blood pressure either alone or with other medicines.

Cardiovascular complications

Heart attack, stroke, diseases of the heart muscle and arteries, heart failure, death or hospitalisation from these conditions can occur more frequently or worsen in elderly patients (55 years or older), especially if they have, or have had, any of the following conditions:

- coronary heart disease (caused by poor blood flow in blood vessels around the heart)
- peripheral vascular disease (poor circulation in the limbs, hands and feet)
- previous stroke
- transient ischaemic attack (TIA, a brief stroke-like attack that resolves quickly, but could lead to stroke)

- diabetes with other high-risk factors and organ damage (e.g. in kidneys, heart, brain, eyes).

Telmisartan helps prevent these complications and death from cardiovascular causes in these high risk patients.

Talk to your doctor about your risk of developing cardiovascular complications and what to do to reduce that risk.

This medicine is available only with a doctor's prescription.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

Do not give this medicine to a child or adolescent under 18 years old.

Its safety and effectiveness in this age group have not been established.

Before you take it

When you must not take it

Do not take this medicine if you have an allergy to telmisartan, or to any of the inactive ingredients listed at the end of this leaflet under Product Description.

Some of the symptoms of an allergic reaction may include shortness of breath; wheezing or difficulty in breathing; swelling of the face, lips tongue or other parts of the body; rash, itching or hives on the skin.

Do not take this medicine if you are, or plan to be, pregnant or breastfeeding.

It may affect your developing baby if you take it during pregnancy.

It is not known if telmisartan passes into breast milk and there is a possibility that your baby may be affected.

Do not take this medicine if you have the following medical conditions:

- severe liver disease
- biliary obstructive disorders (problem with the flow of bile from the gall bladder)
- diabetes or kidney problems and you are taking aliskiren (a medicine used to treat high blood pressure).

Talk to your doctor if you have a history of problems digesting lactose, glucose or galactose.

NOUMED TELMISARTAN tablets contain lactose. It may not be suitable for you.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If you take it after the expiry date has passed, it may not work as well.

If it has expired or is damaged, return the pack to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have, or have had, any of the following medical conditions:

- kidney problems
- liver problems
- heart problems
- diabetes
- a condition known as primary hyperaldosteronism (raised aldosterone levels, also known as Conn's syndrome)
- intolerance to lactose or other sugars (glucose, galactose)
- recent severe diarrhoea or vomiting

Tell your doctor if you are following a very low salt diet.

Tell your doctor if you are pregnant, plan to become pregnant or are breastfeeding.

Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell him/her before you start taking NOUMED TELMISARTAN.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from a pharmacy, supermarket or health food shop.

NOUMED TELMISARTAN and some medicines may interfere with each other, including:

- ramipril or any other medicines used to treat high blood pressure or heart problems
- potassium supplements or potassium-containing salt substitutes
- medicines or salt substitutes which may increase your potassium levels
- diuretics or fluid tablets, medicines used to help the kidneys get rid of salt and water by increasing the amount of urine produced
- nonsteroidal anti-inflammatory agents (medicines used to relieve pain, swelling and other symptoms of inflammation including arthritis) such as aspirin, ibuprofen, naproxen
- lithium, used to treat certain mental illnesses
- digoxin, used to treat heart failure
- trimethoprim, used to treat bacterial infections
- heparin, a blood thinner
- corticosteroids, used to treat inflammatory conditions
- immunosuppressants (medicines used to prevent organ rejection after transplantation), such as ciclosporin or tacrolimus.

These medicines may be affected by NOUMED TELMISARTAN, or may affect how well it works. Some medicines may lower your blood pressure too much when used with telmisartan. You may need to take different amounts of your medicine or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking NOUMED TELMISARTAN.

How to take NOUMED TELMISARTAN

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions, ask your doctor or pharmacist for help.

How much to take

Your doctor or pharmacist will tell you how much NOUMED TELMISARTAN to take each day. This depends on your condition and whether or not you are taking any other medicines.

The usual dose of NOUMED TELMISARTAN for hypertension is one 40 mg tablet once a day. If your blood pressure is still too high after 4-8 weeks of treatment, your doctor may increase your dose to 80 mg a day.

The usual dose for prevention of cardiovascular complications is one 80 mg tablet once a day. Your doctor may suggest a lower or higher dose depending on your response,

Ask your doctor or pharmacist if you are unsure of the correct dose for you.

They will tell you exactly how much to take.

If you take the wrong dose, NOUMED TELMISARTAN may not work as well and your condition may not improve.

How to take it

Swallow the tablet whole with plenty of water.

It does not matter whether you take it with or without food.

When to take it

Take NOUMED TELMISARTAN at about the same time each day, either in the morning or evening.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

How long to take it

Continue taking NOUMED TELMISARTAN until your doctor tells you to stop.

This medicine helps to control your blood pressure, and/or prevent cardiovascular complications from developing, but does not cure your condition.

Therefore, it is important to keep taking it every day even if you feel well or do not notice any signs of cardiovascular problems. You may have to take blood pressure-lowering medicines for the rest of your life. If you stop taking this medicine, your blood pressure may rise again or other problems may emerge.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Otherwise, take the dose as soon as you remember, and then go back to taking it as you would normally.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting unwanted side effects.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else has taken too much NOUMED TELMISARTAN. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Keep this telephone number handy.

If you take too much NOUMED TELMISARTAN, you may feel dizzy, light-headed or faint. Your heartbeat may be faster or lower than usual. You may experience rapid, shallow breathing or cold, clammy skin. This is because your blood pressure is too low.

While you are taking it

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking NOUMED TELMISARTAN.

Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell your doctor and anaesthetist that you are taking this medicine.

It may affect some medicines you receive during surgery.

Tell your doctor immediately if you become pregnant while taking NOUMED TELMISARTAN.

You should not be taking this medicine while you are pregnant.

If you feel that NOUMED TELMISARTAN is not helping your condition, tell your doctor or pharmacist.

Tell your doctor if, for any reason, you have not used NOUMED TELMISARTAN exactly as prescribed.

Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

Things you must not do

Do not stop taking NOUMED TELMISARTAN or change your dosage without checking with your doctor.

Do not take NOUMED TELMISARTAN to treat any other complaints unless your doctor tells you to.

Do not give this medicine to anyone else, even if they have the same condition as you.

Things to be careful of

Be careful when driving or operating machinery until you know how NOUMED TELMISARTAN affects you.

Like other medicines used to treat high blood pressure, NOUMED TELMISARTAN may cause sleepiness, dizziness or light-headedness in some people, especially if you are also taking a diuretic (fluid tablet), another blood pressure lowering medicine or are dehydrated.

If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Be careful when getting up from a sitting or lying position.

Standing up slowly, especially when you get up from a bed or chair, will help your body get used to the change in position and blood pressure.

If this problem continues or gets worse, talk to your doctor.

If you exercise, or if you sweat, or if the weather is hot, you should drink plenty of water.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking NOUMED TELMISARTAN.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- dizziness or lightheadedness when you stand up especially when getting up from a sitting or lying position
- dizziness or spinning sensation, fainting
- tiredness or weakness
- 'flu-like' symptoms
- pain in the chest
- diarrhoea
- indigestion
- stomach pain or discomfort
- wind or excessive gas in the stomach or bowel (flatulence)
- upper respiratory tract infections
- shortness of breath
- back pain
- aching muscles, not caused by exercise (myalgia)
- muscle spasms or leg cramps or leg pain
- painful joints (arthralgia)
- tendon pain or tendinitis-like symptoms
- urinary tract infections (including cystitis)
- trouble sleeping (insomnia)
- feeling anxious
- depression
- fast or slow heart beats
- visual disturbance
- increased sweating
- dry mouth
- allergic skin reactions including skin rash (eczema); itchiness (pruritus); redness of the skin (erythema)
- symptoms that may indicate low blood sugar levels in the blood, such as sweating, weakness, hunger, dizziness, trembling, headache or numbness (especially in diabetic patients)
- abnormal liver functions
- symptoms that may indicate a worsening of the kidney function, such as passing little or no urine, drowsiness, nausea, vomiting, breathlessness, loss of appetite and weakness.
- symptoms that may indicate high potassium levels in the blood, such as

- nausea, diarrhoea, muscle weakness and changes in heart rhythm
- signs of anaemia such as tiredness, being short of breath when exercising, dizziness and looking pale
- bleeding or bruising more easily than normal (thrombocytopenia)
- symptoms that may indicate an infection of the blood, such as high fever, chills, headache confusion and rapid breathing
- changes in your red or white blood cell levels (which are detected by blood tests).

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing
- severe and sudden onset of itchy or raised skin rash, hives or nettle rash

These are serious side effects. You may need urgent medical attention or hospitalisation. These side effects are rare.

Other side effects not listed above may also occur in some people.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

After taking it

Storage

Keep your medicine in the original container until it is time to take them.

If you take the tablets out of its container, they may not keep well.

Keep your medicine in a cool, dry place, protected from light, where the temperature stays below 30°C.

Do not store it, or any other medicine, in the bathroom or near a sink. Do not leave it on a windowsill or in the car.

Heat and dampness can destroy some medicines.

Keep this medicine where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or its expiry date has passed, ask your pharmacist what to do with any tablets that are left over.

Product description

What it looks like

NOUMED TELMISARTAN is available in 2 strengths that are supplied in blister packs of 28 tablets each.

40 mg: white, oblong tablet scored on one side and debossed with '40' on the other side.

80 mg: white, oblong tablet scored on one side and debossed with '80' on the other side.

Ingredients

Active ingredient

NOUMED TELMISARTAN tablets contain either 40 mg or 80 mg of telmisartan.

Inactive ingredients

- lactose

- Ludipress (mixture of lactose monohydrate, povidone and crospovidone)
- povidone
- meglumine
- sodium hydroxide
- magnesium stearate

NOUMED TELMISARTAN does not contain sucrose, gluten, tartrazine or any other azo dyes.

Sponsor

Avallon Pharmaceuticals Pty Ltd
Level 5, 7 Eden Park Drive
Macquarie Park NSW 2113
Telephone 1800 930 999

Australian registration numbers

40 mg: AUST R 298268

80 mg: AUST R 298269

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