

TELMISARTAN HCTZ AN Tablets

Telmisartan and Hydrochlorothiazide

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about TELMISARTAN HCTZ AN.

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

This leaflet was last updated on the date at the end of this leaflet. More recent information may be available.

The latest Consumer Medicine Information is available from your pharmacist, doctor, or from www.medicines.org.au and may contain important information about the medicine and its use of which you should be aware.

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

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

Keep this leaflet with the medicine.

You may need to read it again.

What TELMISARTAN HCTZ AN is used for

TELMISARTAN HCTZ AN is used to lower high blood pressure (hypertension).

Everyone has blood pressure. This pressure helps your blood move around your body. Your blood pressure may be different at different times of the day,

depending on how busy or worried you are.

You have hypertension (high blood pressure) when your blood pressure stays higher than is needed, even when you are calm or relaxed. There are usually no signs of hypertension. The only way of knowing that you have hypertension is to have your blood pressure checked on a regular basis.

If high blood pressure is not treated, it can lead to serious health problems, including stroke, heart disease and kidney failure.

How TELMISARTAN HCTZ AN works

TELMISARTAN HCTZ AN contains telmisartan and hydrochlorothiazide in one single tablet. These two active ingredients help to reduce blood pressure in different ways:

- Telmisartan belongs to a group of medicines called angiotensin II receptor antagonists. Angiotensin II is a substance in the body which causes blood vessels to narrow, thus increasing blood pressure. Telmisartan works by blocking the effect of angiotensin II. When the effect of angiotensin II is blocked, your blood vessels relax and your blood pressure goes down.
- Hydrochlorothiazide belongs to the group of medicines called diuretics. Diuretics help to reduce the amount of excess fluid in the body by increasing the amount of urine produced. They help with lowering blood pressure particularly when used

with other blood pressure lowering medicines.

Your doctor may have prescribed TELMISARTAN HCTZ AN for another reason.

Ask your doctor if you have any questions about why TELMISARTAN HCTZ AN has been prescribed for you.

TELMISARTAN HCTZ AN is not addictive. This medicine is available only with a doctor's prescription.

Use in Children

The safety and effectiveness of TELMISARTAN HCTZ AN in children and teenagers up to 18 years of age have not been established.

Before you take TELMISARTAN HCTZ AN

When you must not take it

Do not take TELMISARTAN HCTZ AN if you have ever had an allergic reaction after taking:

- Telmisartan or hydrochlorothiazide (the two active ingredients in TELMISARTAN HCTZ AN),
- Other sulfonamide-derived medicines
- Any of the other ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction to TELMISARTAN HCTZ AN may include skin rash, itchiness, shortness of breath, swelling of the

face, lips or tongue, muscle pain or tenderness or joint pain.

Do not take TELMISARTAN HCTZ AN if you have a rare hereditary condition of galactose intolerance.

The maximum recommended daily dose of TELMISARTAN HCTZ AN contains 112 mg of lactose (in the 40/12.5 mg and 80/12.5 mg tablets) and 99 mg of lactose (in the 80/25 mg tablets).

Do not take TELMISARTAN HCTZ AN if you are pregnant or intend to become pregnant.

TELMISARTAN HCTZ AN is not recommended for use in pregnancy. Like other similar medicines, it could affect your unborn baby if you take it during pregnancy.

Do not breast-feed if you are taking TELMISARTAN HCTZ AN.

It is not known if telmisartan or hydrochlorothiazide, the active ingredients in TELMISARTAN HCTZ AN, pass into breast milk and there is a possibility that your baby may be affected.

Do not take TELMISARTAN HCTZ AN if you have any of the following medical conditions:

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

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

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

If you are not sure whether you should start taking

TELMISARTAN HCTZ AN, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes

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

- kidney problems
- liver problems
- heart problems
- a condition known as primary hyperaldosteronism (raised aldosterone levels, also known as Conn's syndrome)
- diabetes
- gout
- galactose intolerance
- recent severe diarrhoea or vomiting
- asthma
- systemic lupus erythematosus (a disease affecting the skin, joints and kidney)
- eye problems

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

Tell your doctor if you plan to become pregnant or breastfeed.

If you have not told your doctor about any of the above, tell your doctor before you take TELMISARTAN HCTZ AN.

Taking other medicines

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

Some medicines and TELMISARTAN HCTZ AN may interfere with each other. These include:

- any other medicines used to treat high blood pressure such as beta-blockers

- heart medicines such as digoxin, a medicine used to treat heart failure or antiarrhythmic medicines
- lithium, a medicine used to treat certain mental illnesses
- other diuretics or fluid tablets medicines used to help the kidneys get rid of salt and water by increasing the amount of urine produced
- laxatives
- potassium supplements or potassium-containing salt substitutes
- medicines or salt substitutes which may increase your potassium levels
- amphotericin, a medicine used to treat fungal infections
- penicillin antibiotics, used to treat bacterial infections
- alcohol
- sleeping tablets
- strong pain killing medicines
- medicines for diabetes (oral tablets or capsules or insulin)
- powder or granules used to help reduce cholesterol
- corticosteroid medicines such as prednisolone, cortisone or ACTH
- aspirin
- nonsteroidal anti-inflammatory agents (medicines used to relieve pain, swelling and other symptoms of inflammation including arthritis)
- medicines used to treat gout
- calcium supplements or medicines containing calcium
- anticholinergic medicines, which can be used to treat Parkinson's disease, relieve stomach cramps or prevent travel sickness
- amantadine, a medicine used to treat Parkinson's disease or to prevent influenza
- medicines used to treat cancer (cytotoxic medicines)

These medicines may be affected by TELMISARTAN HCTZ AN, or

may affect the way it works. Also, other medicines used to treat high blood pressure may have an additive effect with TELMISARTAN HCTZ AN in lowering your blood pressure. Therefore, you may need different amounts of your medicines.

Your doctor or pharmacist may have more information on medicines to be careful with or avoid while taking TELMISARTAN HCTZ AN.

How to take TELMISARTAN HCTZ AN

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

They may differ from the information contained in this leaflet. Your doctor or pharmacist will tell you how many tablets you will need to take each day. This depends on your condition and whether or not you are taking any other medicines.

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

How much to take

The usual dose for adults is one TELMISARTAN HCTZ AN 40/12.5 mg tablet once a day. If your blood pressure is still too high after 4-8 weeks of starting treatment, your doctor may increase your dose to one TELMISARTAN HCTZ AN 80/12.5 mg tablet once a day.

If your blood pressure is still not satisfactorily controlled with TELMISARTAN HCTZ AN 80/12.5 mg, your doctor may increase your dose to one TELMISARTAN HCTZ AN 80/25 mg tablet once a day.

It is important to take TELMISARTAN HCTZ AN exactly as your doctor or pharmacist has told you.

When to take it

Take TELMISARTAN HCTZ AN at about the same time each day, either 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.

It does not matter if you take TELMISARTAN HCTZ AN before or after food.

How to take it

Swallow the tablet whole with a full glass of water.

You can take TELMISARTAN HCTZ AN with or without food.

How long to take it

Take TELMISARTAN HCTZ AN every day until your doctor tells you to stop.

TELMISARTAN HCTZ AN helps control your high blood pressure but does not cure it. It is important to keep taking TELMISARTAN HCTZ AN every day even if you feel well.

People who have high blood pressure often feel well and do not notice any signs of this problem.

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

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) for

advice or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much TELMISARTAN HCTZ AN.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too much TELMISARTAN HCTZ AN you may feel dizzy, light-headed or faint. Your heartbeat may be faster or lower than usual. You may experience dehydration, nausea, drowsiness and muscle spasm.

While you are taking TELMISARTAN HCTZ AN

Things you must do

Tell any other doctors, dentists and pharmacists who are treating you that you are taking TELMISARTAN HCTZ AN.

If you are about to be started on any new medicine, tell your doctor or pharmacist that you are taking TELMISARTAN HCTZ AN.

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

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

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

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

You should not take this medicine while you are pregnant.

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

TELMISARTAN HCTZ AN.

TELMISARTAN HCTZ AN may affect some medicines you receive during surgery.

Things you must not do

Do not use TELMISARTAN HCTZ AN to treat other complaints unless your doctor or pharmacist tells you to.

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

Things to be careful of

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

Like other medicines used to treat high blood pressure, TELMISARTAN HCTZ AN may cause sleepiness, dizziness or lightheadedness in some people.

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

You may feel dizzy or light-headed when you begin to take TELMISARTAN HCTZ AN, especially if you are also taking a diuretic (or fluid tablet) or if you are dehydrated.

If this medicine makes you feel dizzy or light-headed, 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 TELMISARTAN HCTZ AN even if you do not think it is connected with the medicine.

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

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have. Tell your doctor if you notice any of the following and they worry you:

- ‘flu-like’ symptoms
- fainting, dizziness or spinning sensation
- a feeling of tension or fullness in the nose, cheeks and behind the eyes, sometimes with a throbbing ache (sinusitis)
- infections of the air passages
- shortness of breath or difficulty breathing
- transient abnormal or blurred vision
- back pain
- changes in heart rhythm or increased heart rate
- rash or redness or itchiness of skin
- increased sweating
- dizziness or lightheadedness when you stand up (postural hypotension)
- stomach pain or discomfort (abdominal pain, dyspepsia, gastritis)
- wind or excessive gas in the stomach or bowel
- vomiting
- diarrhoea or constipation
- dry mouth
- pins and needles

- sleep disturbances or trouble sleeping
- feeling anxious
- depression
- impotence
- leg pain or cramps in legs
- aching muscles or aching joints not caused by exercise or muscle spasms
- chest pain
- pain
- liver problems
- changes in the levels of potassium or sodium or uric acid in your blood (such changes are usually detected by a blood test)

Tell your doctor as soon as possible if you experience any side effects during or after taking TELMISARTAN HCTZ AN, so that these may be properly treated.

Symptoms such as feeling very thirsty, sleepy, sick or vomiting, a dry mouth, general weakness, muscle pain or cramps, a very fast heart rate, may mean that the hydrochlorothiazide part of TELMISARTAN HCTZ AN is having an excessive effect.

You should tell your doctor if you experience any of these symptoms. Tell your doctor immediately or go to the Emergency Department 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 pinkish, itchy swellings on the skin, also called hives or nettle rash
- developing or worsening of a disease called systemic lupus erythematosus which affects the skin, joints and kidney
- sudden loss of vision or eye pain.

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

or hospitalisation. These side effects are rare.

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

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

After taking TELMISARTAN HCTZ AN

Storage

Leave the tablets in the blister strip until it is time to take a dose.

The blister pack protects the tablets from light and moisture.

Keep TELMISARTAN HCTZ AN in a cool, dry place where the temperature stays below 25°C.

Do not store TELMISARTAN HCTZ AN or any other medicine in the bathroom or near a sink.

Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep TELMISARTAN HCTZ AN where young children cannot reach it.

Disposal

If your doctor tells you to stop using TELMISARTAN HCTZ AN or it has passed its expiry date, ask your pharmacist what to do with any that is left over.

Product description

What it looks like

TELMISARTAN HCTZ AN is the brand name of your medicine. TELMISARTAN HCTZ AN tablets are available in three strengths: 40/12.5 mg, 80/12.5 mg and 80/25 mg tablets.

TELMISARTAN HCTZ AN 40/12.5 mg and 80/12.5 mg tablets are pink mottled and white to off-

white biconvex, oval shaped, two layer tablets. The white to off-white layer may contain pink specks.

Each tablet contains either 40 mg or 80 mg of telmisartan and 12.5 mg of hydrochlorothiazide. The pink mottled face of TELMISARTAN HCTZ AN 40/12.5 mg tablets are marked with L199. The pink mottled face of TELMISARTAN HCTZ AN 80/12.5 mg tablets are marked with L200.

TELMISARTAN HCTZ AN 80/25 mg tablets are yellow mottled and white to off-white biconvex, oval shaped, two layer tablets. The white to off-white layer may contain yellow specks. Each tablet contains 80 mg of telmisartan and 25 mg of hydrochlorothiazide. The white face of TELMISARTAN HCTZ AN 80/25 mg tablets are marked with L201. TELMISARTAN HCTZ AN tablets are available in blister packs of 28 tablets.

The following Australian Registration Numbers appear on the carton:

AUST R 221179 for
TELMISARTAN HCTZ AN
40/12.5 mg tablets

AUST R 221180 for
TELMISARTAN HCTZ AN
80/12.5 mg tablets

AUST R 221181 for
TELMISARTAN HCTZ AN 80/25
mg tablets

Ingredients

Each TELMISARTAN HCTZ AN 40/12.5 mg tablet contains 40 mg telmisartan and 12.5 mg hydrochlorothiazide.

Each TELMISARTAN HCTZ AN 80/12.5 mg tablet contains 80 mg telmisartan and 12.5 mg hydrochlorothiazide.

Each TELMISARTAN HCTZ AN 80/25 mg tablet contains 80 mg telmisartan and 25 mg hydrochlorothiazide.

The other ingredients found in the tablets are:

- povidone (K25)
- lactose
- magnesium stearate
- meglumine
- sodium hydroxide
- sodium stearyl fumarate
- mannitol

TELMISARTAN HCTZ AN 40/12.5 mg and 80/12.5 mg tablets also contain Pigment Blend PB-24880 Pink and TELMISARTAN HCTZ AN 80/25 mg tablets also contain Pigment Blend PB-52290 Yellow, as colouring agent.

Sponsor

Amneal Pharma Australia Pty Ltd
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Australia

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