

TELMISARTAN/ AMLODIPINE VIATRIS

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about taking this medicine, speak to your doctor or pharmacist.

1. Why am I taking TELMISARTAN/ AMLODIPINE VIATRIS?

TELMISARTAN/ AMLODIPINE VIATRIS contains the active ingredients telmisartan and amlodipine (as besilate). TELMISARTAN/ AMLODIPINE VIATRIS is used to lower high blood pressure (hypertension). For more information, see Section [1. Why am I taking TELMISARTAN/ AMLODIPINE VIATRIS?](#) in the full CMI.

2. What should I know before I take TELMISARTAN/ AMLODIPINE VIATRIS?

Do not take if you have ever had an allergic reaction to telmisartan, amlodipine or any of the ingredients listed at the end of the CMI. **Talk to your doctor if you have any other medical conditions, take any other medicines or are pregnant or plan to become pregnant or are breastfeeding. Do not take TELMISARTAN/ AMLODIPINE VIATRIS if you have a rare hereditary condition of fructose intolerance and/ or galactose intolerance.**

For more information, see Section [2. What should I know before I take TELMISARTAN/ AMLODIPINE VIATRIS?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with TELMISARTAN/ AMLODIPINE VIATRIS and affect how it works. A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I take TELMISARTAN/ AMLODIPINE VIATRIS?

- Follow all directions given by your doctor or pharmacist, they will tell you how many tablets you will need to take each day.

More instructions can be found in Section [4. How do I take TELMISARTAN/ AMLODIPINE VIATRIS?](#) in the full CMI.

5. What should I know while taking TELMISARTAN/ AMLODIPINE VIATRIS?

Things you should do	Remind any doctor, dentist or pharmacist you visit that you are taking TELMISARTAN/ AMLODIPINE VIATRIS.
Things you should not do	Do not stop taking this medicine or lower the dosage without checking with your doctor.
Driving or using machines	- Be careful driving or operating machinery until you know how this medicine affects you. - TELMISARTAN/ AMLODIPINE VIATRIS may cause dizziness, lightheadedness or tiredness in some people.
Drinking alcohol	Tell your doctor if you drink alcohol. Your doctor may advise you to limit your alcohol intake.
Looking after your medicine	Keep your medicine in a cool dry place where the temperature stays below 25°C.

For more information, see Section [5. What should I know while taking TELMISARTAN/ AMLODIPINE?](#) in the full CMI.

6. Are there any side effects?

Common side effects include feeling light-headed, dizzy or faint, swelling of hands, ankles or feet, tiredness, weakness or difficulty sleeping, tingling, numbness or pain in the hands or feet, pins and needles, headache, taste disturbance or loss of taste, shaking or tremors, slow heartbeat, abnormal or blurred vision, palpitations, low blood pressure, flushed or pale skin, cough, stomach pain, diarrhoea, constipation, change of bowel habits, feeling sick (nausea) or vomiting, tender or enlarged gums, an uncomfortable feeling in the stomach or belching after eating (indigestion), dry mouth, itching, rash, redness of skin, pain in joints, muscle cramps, aching, tender or weak muscles not caused by exercise, back pain, pain in extremity, night-time or frequent urination, difficulty in getting or maintaining an erection, generally feeling unwell, chest pain, feeling anxious or sad, confusion, forgetfulness, unsteadiness, difficult concentrating.

Serious side effects include swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing, severe and sudden onset or itchy or raised skin rash, hives or nettle rash. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

TELMISARTAN/ AMLODIPINE VIATRIS

Active ingredients: telmisartan and amlodipine (as besilate)

Consumer Medicine Information (CMI)

This leaflet provides important information about taking TELMISARTAN/ AMLODIPINE VIATRIS. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking TELMISARTAN/ AMLODIPINE VIATRIS.**

Where to find information in this leaflet:

1. [Why am I taking TELMISARTAN/ AMLODIPINE VIATRIS?](#)
2. [What should I know before I take TELMISARTAN/ AMLODIPINE VIATRIS?](#)
3. [What if I am taking other medicines?](#)
4. [How do I take TELMISARTAN/ AMLODIPINE VIATRIS?](#)
5. [What should I know while taking TELMISARTAN/ AMLODIPINE VIATRIS?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I taking TELMISARTAN/ AMLODIPINE VIATRIS?

TELMISARTAN/ AMLODIPINE VIATRIS contains the active ingredients telmisartan and amlodipine (as besilate).

TELMISARTAN/ AMLODIPINE VIATRIS is taken to lower high blood pressure (hypertension).

Everyone has blood pressure. This pressure helps get your blood all 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 symptoms 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.

Telmisartan and amlodipine (as besilate) help to reduce blood pressure in different ways:

- Telmisartan belongs to a group of medicines called angiotensin II receptor blockers. 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.
- Amlodipine belongs to a group of medicines called calcium channel blockers. Amlodipine blocks calcium from moving into the cells of the heart and blood vessels. As a result, they relax the blood vessels and increase the supply of blood and oxygen to the heart while reducing its workload.

This means that both of these active ingredients work together to help stop your blood vessels tightening. As a result, the blood vessels relax and blood pressure is lowered.

Your doctor may have prescribed it for another reason.

Ask your doctor if you have any questions about why TELMISARTAN/ AMLODIPINE VIATRIS has been prescribed for you.

2. What should I know before I take TELMISARTAN/ AMLODIPINE VIATRIS?

Warnings

Do not take TELMISARTAN/ AMLODIPINE VIATRIS if you:

- You have an allergy to
 - o any medicine containing telmisartan or amlodipine
 - o other medicines belonging to a group of chemicals called dihydropyridines taken to treat blood pressure and other heart problems.
 - o any of the ingredients listed at the end of this leafletSome of the symptoms of an allergic reaction may include:
 - o shortness of breath
 - o wheezing or difficulty breathing
 - o swelling of the face, lips, tongue or other parts of the body
 - o rash, itching or hives on the skin

Always check the ingredients to make sure you can take TELMISARTAN/ AMLODIPINE VIATRIS.

- have any of the following medical conditions:
 - o severe liver disease
 - o biliary obstruction (problems with drainage of the bile from the liver and gall bladder)
 - o aortic stenosis (a narrowing of the aortic heart valve)
 - o cardiogenic shock (a condition where your heart is unable to supply enough blood to the body)
 - o heart failure after having a heart attack (a condition where the heart muscle cannot pump blood strongly enough to supply the blood throughout the body)
 - o severe hypotension (low blood pressure)
 - o diabetes or kidney problems and you are taking aliskiren (a medicine taken to treat high blood pressure)
- **have the rare hereditary condition of fructose intolerance.**

Check with your doctor if you:

- have allergies to any other medicines, foods, preservatives or dyes.
- have any of the following medical conditions:
 - kidney problems
 - kidney transplant
 - liver problems
 - heart problems
 - diabetes
 - a condition known as primary aldosteronism or hyperaldosteronism
 - recent severe diarrhoea or vomiting
 - high levels of potassium in your blood
 - fructose intolerance or mannitol intolerance
- are following a very low salt diet
- are pregnant or plan to become pregnant or are breast-feeding.
Your doctor can discuss with you the risks and benefits involved.
- take any medicines for any other condition

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

Pregnancy and breastfeeding

Do not take TELMISARTAN/ AMLODIPINE VIATRIS if you are pregnant or plan to become pregnant.

Like other similar medicines, it may affect your developing baby if you take it during pregnancy.

Do not take TELMISARTAN/ AMLODIPINE VIATRIS if you are breastfeeding or plan to breastfeed.

One of the active substances in TELMISARTAN/ AMLODIPINE VIATRIS, amlodipine, is known to pass into the breast milk.

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

Do not give TELMISARTAN/ AMLODIPINE VIATRIS to a child under the age of 18 years.

Safety and effectiveness in children younger than 18 years have not been established.

If you are not sure whether you should start taking TELMISARTAN/ AMLODIPINE VIATRIS, talk to your doctor.

3. What if I am taking other medicines?

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

Some medicines may interfere with TELMISARTAN/ AMLODIPINE VIATRIS and affect how it works. These include:

- other medicines taken to treat high blood pressure including fluid tablets or diuretic medicines, ACE inhibitors and aliskiren
- potassium supplements or potassium-containing salt substitutes
- lithium, a medicine taken to treat certain types of depression or mental illness
- non-steroidal anti-inflammatory drugs (NSAIDs), e.g. aspirin or ibuprofen, or COX-2 inhibitors, medicines taken to relieve pain, swelling and other symptoms of inflammation including arthritis
- anticonvulsant agents such as carbamazepine, phenobarbital, phenytoin, primidone (medicine taken to treat epilepsy or fits)
- some antibiotics, such as rifampicin, erythromycin or clarithromycin
- some antifungals, such as ketoconazole and itraconazole
- anti-proteases, medicines taken to treat HIV infection such as ritonavir
- diltiazem (a cardiac medicine)
- heparin (a blood thinning medicine)
- simvastatin (a cholesterol lowering medication)
- herbal medicines derived from St John's wort (*Hypericum perforatum*)
- grapefruit or grapefruit juice
- muscle relaxant such as dantrolene (an infusion for severe body temperature abnormalities)
- immunosuppressants such as ciclosporin or tacrolimus (medicines used to prevent organ rejection after transplantation)
- medicines used to alter the way your immune system works such as sirolimus, temsirolimus and everolimus.

You may need different amounts of your medicines, 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 TELMISARTAN/ AMLODIPINE VIATRIS.

4. How do I take TELMISARTAN/ AMLODIPINE VIATRIS?

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, ask your doctor or pharmacist for help.

How much to take

- The usual dosage is one tablet a day.

Depending on how you respond to the treatment, your doctor may suggest a higher or lower dose.

It is important to take TELMISARTAN/ AMLODIPINE VIATRIS exactly as your doctor or pharmacist has told you.

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

They will tell you exactly how much to take.

Swallow the tablet whole with a full glass of water.

When to take TELMISARTAN/ AMLODIPINE VIATRIS

Take TELMISARTAN/ AMLODIPINE VIATRIS at about the same time each day. 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/ AMLODIPINE VIATRIS before or after food.

How long to take TELMISARTAN/ AMLODIPINE VIATRIS

Continue taking TELMISARTAN/ AMLODIPINE VIATRIS for as long as your doctor tells you.

TELMISARTAN/ AMLODIPINE VIATRIS helps to control your condition but does not cure it. It is important to keep taking your medicine 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 TELMISARTAN/ AMLODIPINE VIATRIS

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 your medicine as you would normally.

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

This may increase the chance of you getting an unwanted side effect.

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 TELMISARTAN/ AMLODIPINE VIATRIS

If you think that you or anyone else has taken too much TELMISARTAN/ AMLODIPINE VIATRIS, urgent medical attention may be needed.

You should immediately:

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

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

Excess fluid may accumulate in your lungs (pulmonary oedema) causing shortness of breath that may develop up to 24-48 hours after intake.

5. What should I know while taking TELMISARTAN/ AMLODIPINE VIATRIS?

Things you should do

- If you are about to be started on any new medicine, remind your doctor, dentist and pharmacist who treat you that you are taking TELMISARTAN/ AMLODIPINE VIATRIS.
- Talk to your doctor if you are elderly and your dose needs to be increased
 - Your doctor may monitor your condition more closely.
- **Make sure you drink enough water during exercise and hot weather when you are taking TELMISARTAN/ AMLODIPINE VIATRIS, especially if you sweat a lot.**
 - If you do not drink enough water while taking TELMISARTAN/ AMLODIPINE VIATRIS, you may feel faint, light-headed or sick. This is because your blood pressure is dropping suddenly.
 - If you continue to feel unwell, tell your doctor.
- **If you have excess vomiting or diarrhoea while taking TELMISARTAN/ AMLODIPINE VIATRIS, tell your doctor.**

You may lose too much water and salt and your blood pressure may drop too much.
- If you are going to have surgery, tell the surgeon or anaesthetist that you are taking TELMISARTAN/ AMLODIPINE VIATRIS.

It may affect other medicines taken during surgery.
- If you are about to have any blood tests, tell your doctor that you are taking TELMISARTAN/ AMLODIPINE VIATRIS.

It may interfere with the results of some tests.
- Keep all of your doctor's appointments so that your progress can be checked.
 - Your doctor may check your blood pressure from time to time to make sure the medicine is working and to prevent unwanted side effects.
 - Your doctor may occasionally do a blood test to check your potassium levels and see how your kidneys are working.

Call your doctor straight away if you:

- **feel light-headed or dizzy after taking your first dose, or when your dose is increased.**

This is especially important if you are taking

TELMISARTAN/ AMLODIPINE VIATRIS for heart failure.

Your blood pressure may drop suddenly.

- become pregnant while taking TELMISARTAN/ AMLODIPINE VIATRIS.

Remind any doctor, dentist or pharmacist you visit that you are taking TELMISARTAN/ AMLODIPINE VIATRIS.

Things you should not do

- Do not take TELMISARTAN/ AMLODIPINE VIATRIS to treat any other complaints unless your doctor tells you to.
- Do not give your medicine to anyone else, even if they have the same condition as you.
- Do not stop taking your medicine or lower the dosage without checking with your doctor.

Things to be careful of

- **If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.**
Standing up slowly, especially when you get up from bed or chairs, 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.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how TELMISARTAN/ AMLODIPINE VIATRIS affects you.

As with other medicines in this class, TELMISARTAN/ AMLODIPINE VIATRIS may cause dizziness, lightheadedness or tiredness in some people.

Make sure you know how you react to TELMISARTAN/ AMLODIPINE VIATRIS before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or light-headed. If this occurs, do not drive.

If you drink alcohol, dizziness or light-headedness may be worse.

Things that would be helpful for your blood pressure

Some self-help measures suggested below may help your condition. Talk to your doctor or pharmacist about these measures and for more information.

- Alcohol - your doctor may advise you to limit your alcohol intake.
- Weight - your doctor may suggest losing some weight to help lower your blood pressure and help lessen the amount of work your heart has to do. Some people may need a dietician's help to lose weight.
- Diet - eat a healthy low-fat diet which includes plenty of fresh vegetables, fruit, bread, cereals and fish. Also eat less fat and sugar.
- Salt - your doctor may advise you to watch the amount of salt in your diet. To reduce your salt intake, you should avoid using salt in cooking or at the table.
- Exercise - regular exercise helps to reduce blood pressure and helps get the heart fitter, but it is important not to overdo it. Walking is good exercise, but find a route that is reasonably flat.

Before starting any exercise, ask your doctor about the best kind of program for you.

- Smoking - your doctor may advise you to stop smoking.

Looking after your medicine

- **Keep your tablets in the original blister strip until it is time to take them.**

The blister pack protects the tablets from light and moisture.

- Store below 25°C.

Follow the instructions on the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

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

Getting rid of any unwanted medicine

If your doctor tells you to stop taking TELMISARTAN/ AMLODIPINE VIATRIS or it is out of date, take it to any pharmacy for safe disposal.

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

6. Are there any side effects?

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

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

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

Less serious side effects

Less serious side effects	What to do
• feeling light-headed, dizzy or faint • swelling of hands, ankles or feet • sleepiness or tiredness, weakness or difficulty sleeping • tingling, numbness or pain in the hands or feet, pins and needles • headache • taste disturbance or loss of taste • shaking or tremors • slow heart beat	Speak to your doctor if you have any of these less serious side effects and they worry you.

Less serious side effects	What to do
• abnormal or blurred vision • palpitations • low blood pressure • flushed or pale skin • cough • stomach pain • diarrhoea • constipation • change of bowel habits • feeling sick (nausea) or vomiting • tender or enlarged gums • an uncomfortable feeling in the stomach or belching after eating (indigestion) • dry mouth • itching, rash, redness of skin • pain in joints • muscle cramps • aching, tender or weak muscles not caused by exercise • back pain, pain in extremity • night-time or frequent urination • difficulty in getting or maintaining an erection • generally feeling unwell • chest pain • feeling anxious or sad • symptoms that may indicate low sodium levels in the blood, such as headache, dizziness, confusion, forgetfulness, weakness, unsteadiness or difficulty concentrating.	

Serious side effects

Serious side effects	What to do
• swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing • severe and sudden onset or itchy or raised skin rash, hives or nettle rash	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

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

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at

www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

TELMISARTAN/ AMLODIPINE VIATRIS is only available with a doctor's prescription.

What TELMISARTAN/ AMLODIPINE VIATRIS contains

Active ingredient (main ingredient)	telmisartan amlodipine (as besilate)
Other ingredients (inactive ingredients)	mannitol sodium hydroxide povidone meglumine magnesium stearate hypromellose titanium dioxide Opacode WB Black NS-78 17821 (ID 12156)
Potential allergens	sulfites.

Do not take TELMISARTAN/ AMLODIPINE VIATRIS if you are allergic to any of these ingredients.

What TELMISARTAN/ AMLODIPINE VIATRIS looks like

TELMISARTAN/ AMLODIPINE VIATRIS 40/5 tablets: white to off-white, film-coated, round shaped, biconvex, bevelled edge tablet imprinted with TM6 using black ink on one side of the tablet and blank on other side. Each tablet contains 40 mg telmisartan and 5 mg amlodipine (AUST R 234915).

TELMISARTAN/ AMLODIPINE VIATRIS 40/10 tablets: white to off-white, film-coated, round shaped, biconvex, bevelled edge tablet imprinted with TM7 using black ink on one side of the tablet and blank on other side. Each tablet contains 40 mg telmisartan and 10 mg amlodipine (AUST R 234903).

TELMISARTAN/ AMLODIPINE VIATRIS 80/5 tablets: white to off-white, film-coated, round shaped, biconvex, bevelled edge tablet imprinted with TM8 using black ink on one side of the tablet and blank on other side. Each tablet contains 80 mg telmisartan and 5 mg amlodipine (AUST R 234913).

TELMISARTAN/ AMLODIPINE VIATRIS 80/10 tablets: white to off-white, film-coated, oval shaped, biconvex, bevelled edge tablet imprinted with TM9 using black ink on one side of the tablet and blank on other side. Each tablet contains 80 mg telmisartan and 10 mg amlodipine (AUST R 234914).

TELMISARTAN/ AMLODIPINE VIATRIS tablets are available to patients in PA/Al/PVC/Al blister packs containing 28 tablets.

Who distributes TELMISARTAN/ AMLODIPINE VIATRIS

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

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