

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 TWILEM?

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

2. What should I know before I take TWILEM?

Do not take if you have ever had an allergic reaction to telmisartan or 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.

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

3. What if I am taking other medicines?

Some medicines may interfere with TWILEM 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 TWILEM?

- Follow all directions given to you by your doctor or pharmacist carefully.
- The usual dose is one tablet a day.
- Swallow the tablet whole with a full glass of water.

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

5. What should I know while taking TWILEM?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are taking TWILEM. • If you feel light-headed or dizzy after taking your first dose of TWILEM, or when your dose is increased, tell your doctor immediately. • If you have excess vomiting or diarrhoea while taking TWILEM, tell your doctor. • If you are going to have surgery, tell the surgeon or anaesthetist that you are taking TWILEM. • If you are about to have any blood tests, tell your doctor that you are taking TWILEM.
Things you should not do	• Do not stop taking TWILEM, or lower the dosage, without checking with your doctor. • Do not take TWILEM to treat any other complaints unless your doctor tells you to. • Do not give TWILEM to anyone else, even if they have the same condition as you.
Driving or using machines	• Be careful driving or operating machinery until you know how TWILEM affects you.
Looking after your medicine	• Keep your tablets in a cool dry place where the temperature stays below 25°C. • Keep your tablets in the original blister strip until it is time to take them in order to protect from moisture.

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

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 TWILEM. If you experience 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 happen, stop taking TWILEM and either tell your doctor immediately or go to Emergency at your nearest hospital. 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.

TWILEM

Active ingredient(s): *Telmisartan and Amlodipine (as besilate)*

Consumer Medicine Information (CMI)

This leaflet provides important information about taking TWILEM. **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 TWILEM.**

Where to find information in this leaflet:

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

1. Why am I taking TWILEM?

TWILEM contains the active ingredients telmisartan and amlodipine (as besilate) 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 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.

TWILEM 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 what 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.

Your doctor may have prescribed TWILEM for another reason.

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

TWILEM is not addictive.

2. What should I know before I take TWILEM?

Warnings

Do not take TWILEM if:

- you are allergic to any medicine containing telmisartan or amlodipine, or other medicines belonging to a group of chemicals called dihydropyridines used to treat blood pressure and other heart problems, or any of the ingredients listed at the end of this leaflet. Some 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 this medicine.

- you 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 used to treat high blood pressure).
- the expiry date printed on the pack has passed.
- the packaging is torn or shows signs of tampering.

Check with your doctor if you:

- have allergies to any other medicines, foods, preservatives or dyes.
- have, or have had, any medical conditions, especially the following:
 - o kidney problems or kidney transplant
 - o liver problems
 - o heart problems
 - o diabetes

- o a condition known as primary aldosteronism or hyperaldosteronism
- o recent severe diarrhoea or vomiting
- o high levels of potassium in your blood
- o are following a very low salt diet.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Do not take TWILEM if you are pregnant.

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

Do not breastfeed if you are taking TWILEM.

One of the active substances in TWILEM, amlodipine, is known to pass into 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.

Use in children

Do not give TWILEM to a child under the age of 18 years.

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

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 and TWILEM may interfere with each other. These include:

- other medicines used 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 used to treat certain types of depression or mental illness
- NSAIDs (non-steroidal anti-inflammatory drugs, e.g. aspirin or ibuprofen) or COX-2 inhibitors, medicines used to relieve pain, swelling and other symptoms of inflammation including arthritis
- anticonvulsant agents such as carbamazepine, phenobarbital, phenytoin, primidone (medicines used to treat epilepsy or fits)
- some antibiotics, such as rifampicin, erythromycin or clarithromycin
- some antifungals, such as ketoconazole or itraconazole
- anti-proteases, medicines used 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.

These medicines may be affected by TWILEM or may affect how well it works. You may need 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 TWILEM.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect TWILEM.

4. How do I take TWILEM?

How much to take

The usual dose 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 TWILEM exactly as your doctor or pharmacist has told you.

When to take TWILEM

- Take TWILEM 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 TWILEM before or after food.

How to take TWILEM

- Swallow the tablet whole with a full glass of water.

How long to take TWILEM

Continue taking TWILEM for as long as your doctor tells you.

TWILEM helps to control your high blood pressure, but does not cure it.

It is important to keep taking TWILEM every day even if you feel well.

If you forget to take TWILEM

TWILEM should be taken regularly at the same time each day.

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

If you take too much TWILEM

If you think that you or anyone else may have taken too much TWILEM, urgent medical attention may be needed.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), 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.

You may need urgent medical attention.

If you take too much TWILEM, 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 TWILEM?

Things you should do

- If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking TWILEM.
- Tell any other doctors, dentists and pharmacists who treat you that you are taking TWILEM.
- 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 TWILEM, especially if you sweat a lot.**

If you do not drink enough water while taking TWILEM, 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 TWILEM, 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 TWILEM.**

It may affect other medicines used during surgery.

- **If you are about to have any blood tests, tell your doctor that you are taking TWILEM.**

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 TWILEM 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 of TWILEM, or when your dose is increased. This is especially important if you are taking TWILEM for heart failure. Your blood pressure may drop suddenly.
- become pregnant while taking TWILEM.

Things you should not do

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

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 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.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how TWILEM affects you.

As with other medicines in this class, TWILEM may cause dizziness, light-headedness or tiredness in some people. Make sure you know how you react to TWILEM 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.

Drinking alcohol

Tell your doctor if you drink alcohol.

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

Looking after your medicine

- Keep your tablets in a cool dry place where the temperature stays below 25°C.
- Keep your tablets in the original blister strip until it is time to take them in order to protect from moisture.

Follow the instructions in 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.

Keep it where young children cannot reach it.

When to discard your medicine

If your doctor tells you to stop taking TWILEM or the expiry date has passed, ask your pharmacist what to do with any that is left over.

Getting rid of any unwanted medicine

If you no longer need to take this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not take this medicine after the expiry date.

6. Are there any side effects?

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.

Less serious side effects

Less serious side effects	What to do
Gastrointestinal related: • stomach pain • diarrhoea	Speak to your doctor or pharmacist if you have any

Less serious side effects	What to do
• constipation • change of bowel habits • an uncomfortable feeling in the stomach or belching after eating (indigestion) Pain related: • headache • pain in joints • muscle cramps • aching, tender or weak muscles not caused by exercise • back pain, pain in extremity • chest pain General well-being related: • 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 • taste disturbances or loss of taste • shaking or tremors • slow heart beat • abnormal or blurred vision • palpitations • low blood pressure • flushed or pale skin • cough • feeling sick (nausea) or vomiting • dry mouth • tender or enlarged gums • itching, rash, redness of skin • night-time or frequent urination • difficulty in getting or maintaining an erection • generally feeling unwell • 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.	of these less serious side effects and they worry you.

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	Call your doctor straight away, or go straight to the Emergency Department at your nearest

Serious side effects	What to do
severe and sudden onset of itchy or raised skin rash, hives or nettle rash.	hospital if you notice any of these serious side effects. These side effects are rare.

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

TWILEM helps most people with high blood pressure, but it may have unwanted side effects in a few people. 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.

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

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

What TWILEM contains

Active ingredient (main ingredient)	- Each TWILEM 40/5 tablet contains 40 mg of telmisartan and 5 mg of amlodipine (as besilate). - Each TWILEM 40/10 tablet contains 40 mg of telmisartan and 10 mg of amlodipine (as besilate). - Each TWILEM 80/5 tablet contains 80 mg of telmisartan and 5 mg of amlodipine (as besilate). - Each TWILEM 80/10 tablet contains 80 mg of telmisartan and 10 mg of amlodipine (as besilate).
Other ingredients (inactive ingredients)	- mannitol - sodium hydroxide - povidone - meglumine - hypromellose - magnesium stearate - microcrystalline cellulose

	- maize starch - macrogol 6000 - colloidal anhydrous silica - crospovidone - sodium bicarbonate - citric acid - croscarmellose sodium - sodium stearyl fumarate
Potential allergens	sulfites

Do not take this medicine if you are allergic to any of these ingredients.

What TWILEM looks like

TWILEM tablets are available in four strengths:

- TWILEM 40/5 tablets are white to off-white, speckled, oval shaped, biconvex, uncoated tablet, debossed with '40/5' on one side and plain on the other side. Approximately 13.40 mm in length and approximately 6.80 mm in width. (AUST R 431299)
- TWILEM 40/10 tablets are white to off-white, speckled, oval shaped, biconvex, uncoated tablet, debossed with '40/10' on one side and plain on the other side. Approximately 13.40 mm in length and approximately 6.80 mm in width. (AUST R 431298)
- TWILEM 80/5 tablets are white to off-white, speckled, oval shaped, biconvex, uncoated tablet, debossed with '80/5' on one side and plain on the other side. Approximately 16.80 mm in length and approximately 8.80 mm in width. (AUST R 431301)
- TWILEM 80/10 tablets are white to off-white, speckled, oval shaped, biconvex, uncoated tablet, debossed with '80/10' on one side and plain on the other side. Approximately 16.80 mm in length and approximately 8.80 mm in width. (AUST R 431300)

Each blister pack contains 28 capsules with or without desiccant.

Who distributes TWILEM

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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