

Twynsta[®]

Tablets

telmisartan/amlodipine besilate

Consumer Medicine Information (CMI)

What is in this leaflet

This leaflet answers some common questions about Twynsta.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

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 taking this medicine, ask 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.

Keep this leaflet with the medicine.

You may need to read it again.

What Twynsta is used for

Twynsta is used 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.

How Twynsta works

Twynsta contains telmisartan and amlodipine (as the besilate salt) 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.

- 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 Twynsta for another reason.

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

Twynsta is not addictive.

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

Before you take Twynsta

When you must not take it

Do not take Twynsta if you have an allergy to:

- any medicine containing telmisartan or amlodipine (the active ingredients in Twynsta)

- other medicines belonging to a group of chemicals called dihydropyridines used to treat blood pressure and other heart problems
- any other ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Do not take Twynsta if you are pregnant.

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

Do not breastfeed if you are taking Twynsta.

One of the active substances in Twynsta, 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.

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

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

Do not take Twynsta if you have any of the following medical conditions:

- severe liver disease
- biliary obstruction (problems with drainage of the bile from the liver and gall bladder)
- aortic stenosis (a narrowing of the aortic heart valve)
- cardiogenic shock (a condition where your heart is unable to supply enough blood to the body)
- 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)
- severe hypotension (low blood pressure)
- diabetes or kidney problems and you are taking aliskiren (a medicine used to treat high blood pressure).

Do not take Twynsta if you have hereditary fructose intolerance.

Twynsta 40/5 mg and 40/10 mg contains 168.64 mg sorbitol in each tablet. Twynsta 80/5 mg and 80/10 mg contains 337.28 mg sorbitol in each tablet.

Do not take Twynsta 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 Twynsta, 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 or 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 sorbitol intolerance.

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

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

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

If you have not told your doctor about any of the above, tell your doctor before you start taking Twynsta.

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 Twynsta 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 Twynsta 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 Twynsta.

How to take Twynsta

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 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 Twynsta exactly as your doctor or pharmacist has told you.

How to take it

Swallow the tablet whole with a full glass of water.

When to take it

Take Twynsta 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 Twynsta before or after food.

How long to take it

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

Twynsta helps to control your high blood pressure, but does not cure it. It is important to keep taking Twynsta 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 an unwanted side effect.

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 (overdose)

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

You may need urgent medical attention.

If you take too much Twynsta, 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.

While you are taking Twynsta

Things you must do

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

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

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 Twynsta, especially if you sweat a lot.

If you do not drink enough water while taking Twynsta, 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 Twynsta, tell your doctor.

You may lose too much water and salt and your blood pressure may drop too much.

If you feel light-headed or dizzy after taking your first dose of Twynsta, or when your dose is increased, tell your doctor immediately.

This is especially important if you are taking Twynsta for heart failure.

Your blood pressure may drop suddenly.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking Twynsta.

It may affect other medicines used during surgery.

If you become pregnant while taking Twynsta, tell your doctor immediately.

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

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 Twynsta 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.

Things you must not do

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

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

Do not stop taking Twynsta, 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 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.

Be careful driving or operating machinery until you know how Twynsta affects you.

As with other medicines in this class, Twynsta may cause dizziness, light-headedness or tiredness in some people. Make sure you know how you react to Twynsta 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 programme for you.
- Smoking - your doctor may advise you to stop smoking.

Side effects

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

Twynsta 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.

Do not be alarmed by the following 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 or pharmacist if you notice any of the following and they worry you:

- 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 disturbances or loss of taste
- shaking or tremors
- slow heart beat
- palpitations
- low blood pressure
- flushed or pale skin
- cough
- stomach pain
- diarrhoea
- 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.

If any of the following happen, stop taking Twynsta and either tell your doctor immediately or go to Emergency at your nearest hospital:

- 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 very 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 that is making you feel unwell.

After taking Twynsta

Storage

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.

Keep your tablets in a cool dry place where the temperature stays below 30°C.

Do not store Twynsta or any other medicine in the bathroom or near a sink.

Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it 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 Twynsta or the expiry date has passed, ask your pharmacist what to do with any tablets that are left over.

Product description

What it looks like

Twynsta is the brand name of your medicine.

Twynsta tablets are available in four strengths: 40/5 mg, 40/10 mg, 80/5 mg and 80/10 mg.

Twynsta 40/5 mg tablets are oval, biconvex shaped two layer tablets, white to off white on one side and blue on the other side. The white side is marked with the Boehringer Ingelheim company logo and 'A1'. The blue side is plain. Available in blister packs of 7 (sample), 14*, 28, 30*, 56* and 98* tablets.

Twynsta 40/10 mg tablets are oval, biconvex shaped two layer tablets, white to off white on one side and blue on the other side. The white side is marked with the Boehringer Ingelheim company logo and 'A2'. The blue side is plain. Available in blister packs of 7 (sample)*, 14*, 28, 30*, 56* and 98* tablets.

Twynsta 80/5 mg tablets are oval, biconvex shaped two layer tablets, white to off white on one side and blue on the other side. The white side is marked with the Boehringer Ingelheim company logo and 'A3'. The blue side is plain. Available in blister packs of 7 (sample), 14*, 28, 30*, 56* and 98* tablets.

Twynsta 80/10 mg tablets are oval, biconvex shaped two layer tablets, white to off white on one side and blue on the other side. The white side is marked with the Boehringer Ingelheim company logo and 'A4'. The blue side is plain. Available in blister packs of 7 (sample), 14*, 28, 30*, 56* and 98* tablets.

* Not currently distributed in Australia

Ingredients

Each Twynsta 40/5 mg tablet contains 40 mg of telmisartan and 5 mg of amlodipine (as the besilate salt) as the active ingredients.

Each Twynsta 40/10 mg tablet contains 40 mg of telmisartan and 10 mg of amlodipine (as the besilate salt) as the active ingredients.

Each Twynsta 80/5 mg tablet contains 80 mg of telmisartan and 5 mg of amlodipine (as the besilate salt) as the active ingredients.

Each Twynsta 80/10 mg tablet contains 80 mg of telmisartan and 10 mg of amlodipine (as the besilate salt) as the active ingredients.

Each Twynsta tablet also contains the following ingredients:

- sodium hydroxide
- povidone
- meglumine

- sorbitol
- magnesium stearate
- microcrystalline cellulose
- pregelatinised maize starch
- maize starch
- colloidal anhydrous silica
- Pigment Blend PB-57699 GREY (as colouring agent).

Supplier

Twynsta tablets are supplied in Australia by:

Boehringer Ingelheim Pty Limited

ABN 52 000 452 308

Sydney, Australia

www.boehringer-ingelheim.com.au

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AUST R 166265

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