

Trajentamet®

Consumer Medicine Information (CMI) summary

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

1. Why am I using Trajentamet?

Trajentamet contains the active ingredients linagliptin and metformin (as hydrochloride). Trajentamet is used to lower blood sugar levels in patients with type 2 diabetes mellitus. For more information, see Section [1. Why am I using Trajentamet?](#) in the full CMI.

2. What should I know before I use Trajentamet?

Do not use if you have ever had an allergic reaction to linagliptin, metformin 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 use Trajentamet?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Trajentamet 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 use Trajentamet?

Your doctor will tell you should take Trajentamet. The usual dose is one Trajentamet tablet twice daily. More instructions can be found in Section [4. How do I use Trajentamet?](#) in the full CMI.

5. What should I know while using Trajentamet?

Things you should do

- Check your blood sugar regularly to tell if your diabetes is being controlled properly.
- Keep all of your doctor's appointments so that your progress can be checked.
- Make sure that you, your family, friends, and work colleagues can recognise the symptoms of hypoglycaemia and

	<p>hyperglycaemia and know how to treat them.</p> <ul style="list-style-type: none"> • Remind any doctor, dentist or pharmacist you visit that you are using Trajentamet. • Be careful when doing activities that can lower your sugar levels such as not eating enough, or when doing unexpected or vigorous exercise
<p>Things you should not do</p>	<ul style="list-style-type: none"> • Do not take Trajentamet to treat any other complaints unless your doctor tells you to. • Do not stop taking your medicine or lower the dosage without checking with your doctor.
<p>Driving or using machines</p>	<ul style="list-style-type: none"> • If your blood sugar level becomes too low, you may feel dizzy, weak or tired and your reaction time may be slower than usual. Other symptoms of low blood sugar are listed under Side effects. If you have any of these symptoms, do not drive, operate machinery or do

	anything else that could be dangerous.
Drinking alcohol	<ul style="list-style-type: none"> Drinking alcohol can increase the risk of your blood sugar levels becoming too low. Talk to your doctor if you drink alcohol.
Looking after your medicine	<ul style="list-style-type: none"> Keep your tablets in the pack until it is time to take them. Keep your tablets in a cool dry place where the temperature stays below 30°C.

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

6. Are there any side effects?

Potential common side effects include, nausea, vomiting, diarrhoea, loss of taste and decreased appetite.

Potential serious side effects include symptoms of low blood sugar (sweating, weakness, hunger, dizziness, trembling, headache, flushing or paleness, numbness, fast pounding heartbeat); symptoms of an allergic reaction (sudden onset of hives or skin rashes, swelling of the face, lips, difficulty breathing); symptoms of an inflamed pancreas (severe stomach pain radiating to the back, vomiting, fever); blisters or breakdown of

skin (erosion). Stop taking Trajentamet if you get any symptoms of lactic acidosis such as feeling cold, weak, light-headed, unexplained weight loss, drowsiness or an irregular heartbeat. 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.

Trajentamet®

Active ingredients: *linagliptin / metformin hydrochloride*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Trajentamet. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Trajentamet.**

Where to find information in this leaflet:

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

1. Why am I using Trajentamet?

Trajentamet contains two different active ingredients linagliptin and metformin. Linagliptin belongs to a class of medicines called DPP-4 inhibitors (dipeptidyl peptidase-4 inhibitors). Metformin belongs to a class of medicines called biguanides.

Trajentamet helps to improve the levels of insulin after a meal and lowers the amount of sugar made by your body.

Lowering and controlling blood sugar may help prevent or delay complications of diabetes, such as heart disease, kidney disease, blindness and foot amputation.

Both medicines work together to control blood sugar in patients with Type 2 diabetes mellitus.

Along with diet and exercise, this medicine helps lower your blood sugar.

Your doctor may have prescribed Trajentamet to replace the antidiabetic medicine(s) you are currently taking. It is important that you continue to follow the diet and/or exercises recommended for you while you are on treatment with Trajentamet.

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 available only with a doctor's prescription. It is not addictive.

Trajentamet is used to lower blood sugar levels in patients with type 2 diabetes mellitus.

It may be used when diet plus exercise do not provide adequate blood sugar level control either:

- alone as a single medicine, or
- in combination with certain other anti-diabetic medicines such as:

- sulfonylurea medicines such as glimepiride and glibenclamide, or
- insulin, or
- sodium-glucose transporter 2 inhibitor medicines such as empagliflozin.

Type 2 diabetes mellitus is also called non-insulin-dependent diabetes mellitus or NIDDM. Type 2 diabetes mellitus develops if the body does not make enough insulin or if the insulin that your body makes does not work as well as it should.

Insulin is a substance which helps to lower the level of sugar in your blood, especially after meals.

When the level of sugar builds up in your blood, this can cause damage to the body's cells and lead to serious problems with your heart, brain, eyes, circulation, nerves or kidneys.

2. What should I know before I use Trajentamet?

Warnings

Do not use Trajentamet if you have an allergy to:

- any medicine containing linagliptin or metformin
- any of the ingredients listed at the end of this leaflet

Some of the 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 Trajentamet if you:

- have any type of metabolic acidosis such as lactic acidosis, diabetic ketoacidosis (a symptom of uncontrolled diabetes, in which substances called ketone bodies build up in the blood - you may notice this as an unusual fruity odour on your breath, difficulty breathing, confusion and frequent urination)
- have had a diabetic pre-coma
- have problems with your kidneys
- have liver problems
- have a severe infection
- are dehydrated
- are treated for acute heart failure or have recently had a heart attack
- have severe problems with your circulation (such as shock)
- have severe breathing difficulties
- have blood clots in the lungs (symptoms include coughing, shortness of breath, chest pain and a fast heart rate)
- have significant blood loss
- have gangrene

- have inflammation of the pancreas (pancreatitis), symptoms include severe upper stomach pain, often with nausea and vomiting
- drink excessive alcohol (all the time or "binge" drinking).

Talk to your doctor about when to stop taking Trajentamet and when to start taking it again if you:

- are going to have an x-ray where you will be injected with an iodinated contrast (dye)
- are planning to have surgery (including where the use of insulin is essential).

Do not give this medicine to a child under the age of 18 years

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

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

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

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

Do not take this medicine if you are pregnant or intending to become pregnant.

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

Do not breast-feed if you are taking this medicine.

One of the active substances in Trajentamet, metformin, is known to pass into human breast milk. It is not known if the other active substance, linagliptin passes into human breast milk and could affect your baby.

Before you start to take it

Discard any other medicines containing metformin or linagliptin that your doctor might have prescribed to you in the past and that you may still have in your possession.

Trajentamet contains linagliptin and metformin. If you have more than one metformin-containing medicine in your possession you may accidentally take too much (overdose). Accidentally taking too much metformin can cause a very serious side effect called lactic acidosis.

ACCIDENTAL METFORMIN OVERDOSING IS A SIGNIFICANT SAFETY RISK.

Ask your doctor or pharmacist if you are unsure if you have any other medicines containing metformin.

Metformin is sold under many different brand names in Australia. Your doctor or pharmacist will know which other medicines also contain metformin.

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

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

Tell your doctor if you have type 1 diabetes, a condition where your body does not produce any insulin.

Trajentamet should not be used to treat type 1 diabetes.

Tell your doctor if you have a known or suspected mitochondrial disease e.g. Mitochondrial Encephalopathy with Lactic acidosis, and Stroke-like episodes (MELAS) or Maternal Inherited Diabetes and Deafness (MIDD).

Trajentamet should not be used as it may increase your risk of lactic acidosis and may worsen your condition

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

If you have not told your doctor, pharmacist or diabetes educator about any of the above, tell them before you take Trajentamet.

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 Trajentamet may interfere with each other. These include:

- an antibiotic used to treat certain infections such as tuberculosis (rifampicin)
- a medicine used to treat reflux and ulcers (cimetidine)
- medicines used to control fits (seizures), chronic pain or glaucoma (carbamazepine, phenobarbital, phenytoin, topiramate, zonisamide, acetazolamide, dichlorphenamide)
- medicines used to treat diseases that involve inflammation, like asthma and arthritis (corticosteroids)
- specific medicines for the treatment of high blood pressure (ACE inhibitors, angiotensin II receptor antagonists, calcium channel blockers, beta blockers)
- medicines used to prevent blood clots, such as warfarin
- medicines which increase urine production (diuretics)
- some medicines used to treat asthma (salbutamol or terbutaline)
- medicines used to relieve pain, swelling and other symptoms of inflammation (NSAIDs (non-steroidal anti-inflammatory drugs) such as aspirin, diclofenac,

ibuprofen, meloxicam, naproxen or piroxicam, and selective COX II inhibitors such as celecoxib, parecoxib, etoricoxib)

- iodinated contrast agents (which you may receive while having an X-ray)
- alcohol-containing medicines
- a medicine used in people with multiple sclerosis, and in young children to treat some types of seizures (fits) (tetracosactrin)
- a medicine used to treat endometriosis (danazol)
- a medicine used to treat schizophrenia and other mental illnesses (chlorpromazine)
- medicines used in the treatment of HIV and chronic hepatitis C infections (dolutegravir, daclatasvir)
- medicines used in the treatment of certain cancers (crizotinib, olaparib, vandetanib).

These medicines may be affected by Trajentamet or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor, pharmacist or diabetes educator can tell you what to do if you are taking any of these medicines. They also have more information on medicines to be careful with or avoid while taking this medicine.

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

4. How do I use Trajentamet?

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 on the box, ask your doctor or pharmacist for help.

How much to take

- Your doctor will tell you how many Trajentamet tablets to take and how often you should take them.
- The usual dose is one Trajentamet tablet twice daily.
- Take Trajentamet exactly as your doctor or pharmacist has told you.
- Your doctor will prescribe Trajentamet alone or in combination with another anti-diabetic medicine if that medicine alone is not sufficient to control your blood sugar level.

When to take Trajentamet

Take your medicine 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.

How to take Trajentamet

Swallow the tablet whole with a full glass of water during or after meals.

This will lessen the chance of a stomach upset.

How long to take it

Continue taking Trajentamet for as long as your doctor tells you to. Make sure you keep enough Trajentamet to last over weekends and holidays.

Trajentamet will help control your diabetes, but will not cure it. Therefore, you may have to take it for a long time.

If you forget to use Trajentamet

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

If you use too much Trajentamet

If you think that you have used too much Trajentamet, you may need urgent medical attention.

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.

5. What should I know while using Trajentamet?

Things you should do

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

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

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

It may affect other medicines used during surgery such as, iodinated contrast agents (which you may receive while having an X-ray).

If you are intending to become pregnant or are pregnant talk to your doctor about alternative medications to control your blood glucose level. It is important your blood glucose levels are as close to normal as possible at this time.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may want to perform blood tests to check your kidneys and vitamin B12 levels while you are taking Trajentamet.

Follow your doctor's and/ or dietician's advice on diet, drinking alcohol and exercise.

Diet and exercise can help your body use its blood sugar better. **It is important to stay on the diet and exercise program recommended by your doctor while taking Trajentamet.**

Make sure you check your blood glucose levels regularly.

This is the best way to tell if your diabetes is being controlled properly. Your doctor or diabetes educator will show you how and when to do this.

Tell your doctor if you become ill or dehydrated, or experience stress, injury, fever, infection, or need surgery.

Your blood glucose may become difficult to control at these times. You may also be at greater risk of developing a serious condition called lactic acidosis. During these times, your doctor may temporarily replace Trajentamet with insulin.

Make sure that you, your friends, family and work colleagues can recognise the symptoms of hypoglycaemia (low blood sugar) and hyperglycaemia (high blood sugar) and know how to treat them.

HYPOGLYCAEMIA

Trajentamet does not normally cause hypoglycaemia, although you may experience it if you take certain other medicines. Be careful when doing any of the following things.

Signs of hypoglycaemia may include:

- weakness, trembling or shaking
- sweating
- light-headedness, dizziness, headache or lack of concentration
- irritability, tearfulness or crying
- hunger
- numbness around the lips and tongue.

If not treated quickly, these symptoms may progress to:

- loss of co-ordination
- slurred speech
- confusion

- fits or loss of consciousness.

At the first signs of hypoglycaemia, you need to raise your blood glucose quickly.

You can do this by taking one of the following:

- 5 -7 jelly beans
- 3 teaspoons of sugar or honey
- half a can of non-diet soft drink
- 2-3 concentrated glucose tablets.

Unless you are within 10 to 15 minutes of your next meal or snack, follow up with extra carbohydrates such as plain biscuits, fruit or milk.

Taking this extra carbohydrate will prevent a second drop in your blood glucose level.

HYPERGLYCAEMIA

If you notice the return of any signs of hyperglycaemia, contact your doctor immediately. The risk of hyperglycaemia is increased in the following situations:

- uncontrolled diabetes
- illness, infection or stress
- taking less Trajentamet than prescribed
- taking certain other medicines
- too little exercise
- eating more carbohydrates than normal.

Things you should not do

Do not take Trajentamet 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.

Do not stop taking your medicine or lower the dosage without checking with your doctor.

Driving or using machines

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

You may experience dizziness when taking Trajentamet.

If your blood sugar level becomes too low, you may feel dizzy, weak or tired and your reaction time may be slower than usual. Other symptoms of low blood sugar are listed under Side effects.

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

Things to be careful of

Be careful when doing any of the following things, which increase the risk of your blood glucose becoming too low:

- drinking alcohol
- not eating enough

- doing unexpected or vigorous exercise.

Looking after your medicine

Storage

Keep your tablets in the pack until it is time to take them.

If you take the tablets out of the pack they may not keep well.

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

Do not store Trajentamet 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.

When to discard your medicine

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

Do not use this medicine after the expiry date.

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 Trajentamet.

This medicine helps most people with type 2 diabetes mellitus, but it may have unwanted side effects in a few people.

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.

Side effects

Side effects	What to do
<ul style="list-style-type: none">• swelling of the nose or throat (nasopharyngitis)• cough• loss in appetite• nausea, vomiting• loss of taste• mouth ulceration• diarrhoea• painful, swollen joints	Tell your doctor or pharmacist if notice any of the following and they worry you.

Side effects	What to do
<ul style="list-style-type: none"> • aching muscles, muscle tenderness or weakness, not caused by exercise • weight gain • constipation <p>Constipation may occur in patients who already take another medication to treat diabetes, such as insulin.</p>	

Serious side effects

Serious side effects	What to do
<p>Symptoms of low blood sugar</p> <ul style="list-style-type: none"> • sweating • weakness • hunger • dizziness • trembling • headache • flushing or paleness • numbness • a fast, pounding heartbeat 	<p>Tell your doctor as soon as possible if you notice any of the symptoms</p> <p>Tell your doctor immediately if you notice any of these symptoms.</p>

Serious side effects	What to do
<p>Low blood sugar may occur in patients who already take another medication to treat diabetes, such as a sulfonylurea or insulin. The dose of your sulfonylurea or insulin medicine may need to be reduced while taking Trajentamet.</p> <p>Symptoms of a skin reaction called bullous pemphigoid</p> <ul style="list-style-type: none"> • development of blisters • breakdown of the outer layer of your skin (erosion) 	<p>Your doctor may tell you to stop taking Trajentamet.</p>

Very serious side effects

Very serious side effects	What to do
<p>Symptoms of an allergic reaction</p> <ul style="list-style-type: none"> • sudden onset of hives, itching or skin rash 	<p>Tell your doctor or go to the Emergency if you notice any of the symptoms</p>

Very serious side effects	What to do
<ul style="list-style-type: none"> • swelling of the face, lips or tongue which may lead to difficulty swallowing or breathing <p>Symptoms of an inflamed pancreas</p> <ul style="list-style-type: none"> • severe upper stomach pain radiating to the back • nausea • vomiting and fever <p>Symptoms of lactic acidosis</p> <ul style="list-style-type: none"> • feeling cold (especially in your arms and legs) • feeling very weak, tired • feeling light-headed, dizzy • severe nausea or vomiting • feeling uncomfortable • muscle pain • drowsiness • abdominal pain • unexplained weight loss 	<p>Stop taking Trajentamet and go to Emergency immediately</p>

Very serious side effects	What to do
<ul style="list-style-type: none"> • irregular heartbeat • rapid or difficult breathing. <p>In rare cases, metformin, one of the active substances in Trajentamet, can cause a serious side effect called lactic acidosis. This is a medical emergency that can cause death. It is caused by a build-up of lactic acid in your blood.</p> <p>The risk of lactic acidosis is higher in the elderly, those whose diabetes is poorly controlled, those with prolonged fasting, those with certain heart conditions, those who drink alcohol, those with kidney disease or liver problems and those with mitochondrial diseases.</p>	

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.

Some of these side effects (e.g. reduced vitamin B12 level) can only be found when your doctor does tests from time to time to check your progress.

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 Trajentamet contains

Active ingredient (main ingredient)	Linagliptin metformin hydrochloride
	<ul style="list-style-type: none">• Each Trajentamet 2.5mg/500mg tablet contains 2.5mg of

	<p>linagliptin and 500mg metformin hydrochloride</p> <ul style="list-style-type: none"> • Each Trajentamet 2.5mg/850mg tablet contains 2.5mg of linagliptin and 850mg metformin hydrochloride • Each Trajentamet 2.5mg/1000mg tablet contains 2.5mg of linagliptin and 1000mg of metformin hydrochloride
<p>Other ingredients (inactive ingredients)</p>	<ul style="list-style-type: none"> • arginine • copovidone • magnesium stearate • maize starch • colloidal anhydrous silica • hypromellose • titanium dioxide • purified talc • iron oxide yellow • iron oxide red • propylene glycol

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

What Trajentamet looks like

Trajentamet is the brand name of your medicine.

Trajentamet 2.5mg/500mg (AUST R 195088 (blister packs) and AUST R 195100 (bottles)) are oval, biconvex light yellow film-coated tablets. They have "D2/500" debossed on one side and the Boehringer Ingelheim logo debossed on the other.

Trajentamet 2.5mg/850mg (AUST R 195101 (blister packs) and AUST R 195106 (bottles)) are oval, biconvex light orange film-coated tablets. They have "D2/850" debossed on one side and the Boehringer Ingelheim logo debossed on the other.

Trajentamet 2.5mg/1000mg (AUST R 195107 (blister packs) and AUST R 195090 (bottles)) are oval, biconvex light pink film-coated tablets. They have "D2/1000" debossed on one side and the Boehringer Ingelheim logo debossed on the other.

Trajentamet is available in blister packs containing 10, 14, 28, 30, 56, 60, 84, 90, 98, 100 and 120 tablets; and in HDPE bottles containing 14, 60 and 180 film-coated tablets.

Not all pack sizes and presentations are available.

Who distributes Trajentamet

Trajentamet is supplied in Australia by:

Boehringer Ingelheim Pty Limited

ABN 52 000 452 308

Sydney NSW

www.boehringer-ingelheim.com.au

This Consumer Medicine Information was updated in January 2026.

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