Trajenta®

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 Trajenta?

Trajenta contains the active ingredient linagliptin. Trajenta is used to lower blood sugar levels in patients over the age of 18 years 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 medication or in combination with other anti-diabetic medicines. Trajenta helps to improve the levels of insulin after a meal and lowers the amount of sugar made by the body. Lowering and controlling blood sugar levels help to prevent complications of diabetes. For more information, see Section 1. Why am I using Trajenta? in the full CMI.

2. What should I know before I use Trajenta?

Do not take if you have ever had an allergic reaction to linagliptin or any of the ingredients listed at the end of the CMI. Do not give to patients under the age of 18 years. **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 Trajenta? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Trajenta 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 Trajenta?

Do not take if you have ever had an allergic reaction to linagliptin or any of the ingredients listed at the end of the CMI. Do not give to patients under the age of 18 years. More instructions can be found in Section 4. How do I use Trajenta? in the full CMI.

5. What should I know while using Trajenta?

Things you should do	• Check your blood sugar levels regularly to tell if your diabetes is being controlled properly. • Be careful when doing activities that can lower your sugar levels, such as drinking alcohol, not eating enough, or exercising suddenly or vigorously. • Remind any doctor, dentist or pharmacist you visit that you are taking Trajenta.
Things you should not do	• Do not take Trajenta to treat any other complaints unless your doctor tells you to. • Do not give Trajenta to anyone else, even if they have the same condition as you.
Driving or using machines	• Be careful before you drive or use any machines or tools until you know how Jardiance affects you. You may experience dizziness when taking Trajenta.
Drinking alcohol	• 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	• Keep your tablets in the original blister strip 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 Trajenta? in the full CMI.

6. Are there any side effects?

Some potential less serious side effects include headaches, aching muscles, mouth ulceration and symptoms of a urinary tract infection (such as frequent urge to urinate in small amounts, painful burning when passing urine). Some potential serious side effects that may require immediate medical attention include symptoms of low blood sugar (such as sweating, weakness, hunger, dizziness, trembling, headache, numbness, fast, pounding heartbeat), a skin reaction called bullous pemphigoid (development of blisters, breakdown of outer layer of skin), allergic reactions (such as hives, swelling of face, lips or tongue which may lead to difficulty swallowing or breathing) and pancreatitis (severe upper stomach pain radiating to back, nausea, vomiting, fever).
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.

Trajenta®

Active ingredient: *linagliptin*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Trajenta. **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 Trajenta.**

Where to find information in this leaflet:

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

1. Why am I using Trajenta?

Trajenta contains the active ingredient linagliptin. Trajenta is a member of a class of medicines you take by mouth called DPP-4 (dipeptidyl peptidase-4) inhibitors that lowers blood sugar levels in patients with type 2 diabetes mellitus.

Trajenta 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.

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

Your doctor will prescribe Trajenta alone, or in combination with another anti-diabetic medicine if that medicine alone is not sufficient to control your blood sugar level. It is important that you continue to follow the diet and/or exercises recommended for you while you are on treatment with Trajenta.

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

Trajenta 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:
    - metformin, or sulfonylurea medicines such as glimepiride and glibenclamide, or
    - insulin (with or without metformin), or metformin plus sulfonylurea medicines, or metformin plus 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 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 that 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 Trajenta?

Warnings

Do not use Trajenta if you have an allergy to:

- any medicine containing linagliptin (the active ingredient in Trajenta)
- any of the other 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 give this medicine to a child or adolescent under the age of 18 years.

Safety and effectiveness in children younger than 18 years old have not been established. Trajenta has not been studied in children younger than 10 years of age.

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.

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:

- type 1 diabetes (also known as 'juvenile onset' or 'insulin-dependent' diabetes mellitus or 'IDDM'), a condition where your body does not produce any insulin

- diabetic ketoacidosis, a condition where chemicals called ketones build up in the body or urine due to very low insulin levels, and results in high blood sugar, rapid weight loss, nausea or vomiting.

Trajenta is not a substitute for insulin. Trajenta should not be used to treat type 1 diabetes or diabetic ketoacidosis.

If you are not sure whether any of the above conditions apply to you, your doctor can advise you.

Alcohol, diet, exercise, and your general health all strongly affect the control of your diabetes.

Discuss these things with your doctor.

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

Your doctor may want to take special precautions if you have any of the above conditions.

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

Tell your doctor if you are pregnant or intend to become pregnant.

Your doctor will discuss the possible risks and benefits involved.

Tell your doctor if you are breast-feeding or planning to breast-feed.

Trajenta is usually not recommended while you are breast-feeding. It is not known if the active ingredient of Trajenta will pass into human breast milk and could affect your baby.

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 Trajenta may interfere with each other. These include:

- rifampicin (an antibiotic medicine used to treat certain infections such as tuberculosis)
- carbamazepine, phenobarbital or phenytoin (medicines used to control fits (seizures) or chronic pain).

These medicines may be affected by Trajenta 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 Trajenta.

4. How do I use Trajenta?

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

The usual dose is one 5 mg tablet once daily.

Take Trajenta exactly as your doctor or pharmacist has told you.

Your doctor will prescribe Trajenta alone, or in combination with another anti-diabetic medicine, if that medicine alone is not sufficient to control your blood sugar level.

How to take it

Swallow the tablet with a full glass of water.

When to take it

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.

It does not matter if you take this medicine before or after food.

How long to take it for

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

Trajenta 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 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 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 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 use too much Trajenta

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

You should immediately:

- **telephone your doctor or Poisons Information Centre (in Australia telephone 13 11 26; in New Zealand telephone 0800 764 766) for advice, 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.

5. What should I know while using Trajenta?

Things you should do

- **If you are about to be started on any new medicine, tell your doctor or pharmacist that you are taking Trajenta.**
- **Tell all doctors, dentists and pharmacists who are treating you that you are taking Trajenta.**
- **If you become pregnant while taking this medicine, tell your doctor immediately.**
- **Keep all of your doctor's appointments so that your progress can be checked.**

  Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.
- **Carefully 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 Trajenta.
- **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 experience stress, injury, fever, infection or need surgery.**

  Your blood glucose may become difficult to control at these times.
- **Make sure that you, your friends, family and work colleagues can recognise the symptoms of hypoglycaemia and hyperglycaemia and know how to treat them.**

HYPOGLYCAEMIA

Trajenta does not normally cause hypoglycaemia, although you may experience it if you take certain other medicines.

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 Trajenta than prescribed
- taking certain other medicines
- too little exercise
- eating more carbohydrates than normal.

Things you should not do

Do not take Trajenta 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.

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.

Driving or using machines

Be careful driving or operating machinery while you are taking Trajenta until you know how it affects you.

You may experience dizziness when taking Trajenta.

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

Tell your doctor if you drink alcohol.

Alcohol may increase the risk of your blood glucose becoming too low.

Looking after your medicine

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

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.

- 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 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?

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
Symptoms of a urinary tract infection • urge to urinate frequently and in small amounts. • painful burning when passing urine. Urinary tract infections may occur in patients who already take another medication to treat diabetes, such as a sulfonylurea. **Symptoms relating to the muscle:** • aching muscles • muscle tenderness • muscle weakness not caused by exercise **Other less serious side effects:** • swelling of the nose or throat (nasopharyngitis) • mouth ulceration • cough • painful, swollen joints • back pain • headache • constipation Constipation may occur in patients who already take another medication to treat diabetes, such as insulin.	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Serious side effects

Serious side effects	What to do
Symptoms of low blood sugar such as: • sweating • weakness • hunger • dizziness • trembling • headache • flushing or paleness • numbness • a fast, pounding heartbeat 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 Trajenta. **Symptoms of a skin reaction called bullous pemphigoid:** • development of blisters • breakdown of outer layer of your skin (erosion) If you experience symptoms of this skin reaction your doctor may tell you to stop taking Trajenta.	**Call your doctor immediately if you notice any of these serious side effects.**

Very serious side effects

Very serious side effects	What to do
Symptoms of an allergic reaction: • sudden onset of hives, itching or skin rash • swelling of the face, lips or tongue which may lead to difficulty swallowing or breathing **Symptoms of an inflamed pancreas - pancreatitis** • severe upper stomach pain radiating to the back	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these very serious side effects.**

Very serious side effects	What to do
• nausea • vomiting • fever	

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 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 Trajenta contains

Active ingredient (main ingredient)	linagliptin 5 mg
Other ingredients (inactive ingredients)	• mannitol • pregelatinised maize starch • maize starch • copovidone • magnesium stearate • Opadry Pink 02F34337 (as colouring agent).

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

What Trajenta looks like

Trajenta is the brand name of your medicine.

Trajenta 5 mg tablets (AUST R 175499) are light red, round, biconvex, bevel-edged film-coated tablets, marked with the BI company logo on one side and 'D5' on the other.

Trajenta tablets are available in blister packs of 10 (sample) and 30 tablets.

Who distributes Trajenta

Trajenta tablets are 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 June 2025.

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