

Trajenta[®]

Tablets

linagliptin

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Trajenta.

It does not contain all the available information.

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

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Trajenta against the benefits they expect it will 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 (Australia) and www.medsafe.govt.nz/Consumers/cmi/CMIForm.asp (New Zealand) 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 Trajenta is used for

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.

How Trajenta works

Trajenta contains the active ingredient linagliptin, which 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.

Before you take Trajenta

When you must not take it

Do not take 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 and adolescents less 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.

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 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.

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.

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 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.

How to take 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

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 take too much (overdose)

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

Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Trajenta. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking Trajenta

Things you must 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 must 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 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.

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.

Side effects

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

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. 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 this 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:

- swelling of the nose or throat (nasopharyngitis)
- mouth ulceration
- cough
- painful, swollen joints
- back pain
- headache

- aching muscles, muscle tenderness or weakness not caused by exercise
- symptoms of urinary tract infection (such as an 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.

- constipation.

Constipation may occur in patients who already take another medication to treat diabetes, such as insulin.

Tell your doctor as soon as possible if you notice any of the 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.

Tell your doctor immediately if you develop blisters or the breakdown of the outer layer of your skin (erosion).

These may be signs of a skin reaction called bullous pemphigoid. Your doctor may tell you to stop taking Trajenta.

Tell your doctor immediately or go to Emergency if you notice any of the following:

- sudden onset of hives, itching or skin rash
- swelling of the face, lips or tongue which may lead to difficulty swallowing or breathing

- severe upper stomach pain radiating to the back, nausea, vomiting, or fever (which may be symptoms of an inflamed pancreas - pancreatitis).

Tell your doctor or pharmacist if you notice anything else that is making you unwell.

Other side effects not listed above may also 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.

After taking Trajenta

Storage

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.

Do not store Trajenta or any other medicine in the bathroom or near a sink. Do not leave it in the car or on a window sill.

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 this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product Description

What it looks like

Trajenta is the brand name of your medicine.

Trajenta tablets 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.

Ingredients

Each Trajenta tablet contains 5 mg of linagliptin as the active ingredient.

Inactive ingredients:

- mannitol
- pregelatinised maize starch
- maize starch
- copovidone
- magnesium stearate
- Opadry Pink 02F34337 (as colouring agent).

Supplier

Trajenta tablets are supplied in Australia by:

Boehringer Ingelheim Pty Limited
ABN 52 000 452 308
78 Waterloo Road
North Ryde NSW 2113

They are supplied in New Zealand by:

Boehringer Ingelheim (N.Z.) Limited
Auckland

This Consumer Medicine Information was updated in July 2017.

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Australian Registration Number

AUST R 175499