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.

Tell 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.

Trafenta 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')
- type 2 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 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
ynecoses Information Centre (in Australia
phone 13 11 26; in New Zealand
phone 0800 764 766) for advice, or go
to Emergency at the nearest hospital, and 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
• 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: