

TRULICITY®

Single dose Pre-filled Pen (autoinjector)

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 TRULICITY?

TRULICITY contains the active ingredient dulaglutide (rch). In adults with Type 2 diabetes, TRULICITY is used to improve blood sugar control and reduce the risk of major adverse cardiovascular events in patients with multiple risk for, or existing cardiovascular disease.

For more information, see Section [1. Why am I using TRULICITY?](#) in the full CMI.

2. What should I know before I use TRULICITY?

Do not use if you have ever had an allergic reaction to TRULICITY 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 TRULICITY?](#).

3. What if I am taking other medicines?

Some medicines may interfere with TRULICITY 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 TRULICITY?

- The recommended starting dose of TRULICITY is 1.5 mg once weekly.
- TRULICITY should be used once weekly at any time of the day, with or without meals.
- More instructions can be found in Section [4. How do I use TRULICITY?](#) in the full CMI.

5. What should I know while using TRULICITY?

Things you should do

- Remind any doctor, dentist, pharmacist or diabetes nurse educator you visit that you are using TRULICITY.
- Always carry glucose or sugary foods with you. Tell your doctor if you

	experience low blood sugar.
Things you should not do	<ul style="list-style-type: none"> • Do not stop using this medicine suddenly and without consulting your Doctor/Healthcare provider. • Do not use this medicine if you think it has been frozen or exposed to excessive heat.
Driving or using machines	<ul style="list-style-type: none"> • Be careful before you drive or use machines or tools until you know how TRULICITY affects you.
Drinking alcohol	<ul style="list-style-type: none"> • Tell your doctor if you drink alcohol. Alcohol may mask the symptoms of low blood sugar (hypoglycaemia), or make it worse.
Looking after your medicine	<ul style="list-style-type: none"> • Keep TRULICITY pens in a fridge between 2°C - 8°C. Do not freeze. • Keep TRULICITY pens in the original pack until ready to use.

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

6. Are there any side effects?

Nausea, diarrhoea, abdominal (stomach) pain and vomiting were very commonly reported in patients using TRULICITY. These side effects are usually not severe and are most common when first starting TRULICITY but decrease over time in most patients.

Serious side effects may include severe low blood sugar, dehydration, gallbladder complaints, and sudden inflammation of the pancreas (severe abdominal pain is the predominant symptom.).

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.

TRULICITY® (TRU-li-si-tee)

Single dose Pre-filled Pen (autoinjector)

Active ingredient(s): *dulaglutide (rch)*

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I using TRULICITY?

TRULICITY contains the active ingredient dulaglutide (rch). TRULICITY is a type of medicine called 'GLP-1 receptor agonists', which are used to help treat diabetes.

Diabetes is a condition in which your pancreas does not produce enough insulin to control your blood sugar level. TRULICITY helps your body to produce more insulin when your blood sugar level is high.

In adults with Type 2 diabetes, TRULICITY is used to improve blood sugar control and reduce the risk of major adverse cardiovascular events in patients with or without existing cardiovascular disease.

TRULICITY may be used alone or with other medicines to control your blood sugar levels. Your doctor may want you to use one or more other medicines in addition to TRULICITY, such as metformin, sulfonylurea, thiazolidinedione (TZD) or insulin.

TRULICITY has not been studied in children.

2. What should I know before I use TRULICITY?

Warnings

Do not use TRULICITY if:

- you are allergic to dulaglutide, or any of the ingredients listed at the end of this leaflet. Check the ingredients in section [7. Product Details](#) to make sure you can use this medicine. Signs of an allergic reaction include redness, swelling and itching at the injection site, rash, shortness of breath, fast pulse or sweating.
- if the packaging is torn or shows signs of tampering.

- if you are experiencing low blood sugar (hypoglycaemia). (See additional information in section [5. What Should I know while using TRULICITY?](#))
- if the product appears cloudy, discoloured, contains particles, or has been frozen or exposed to excessive heat.
- if the expiry date on the pack has passed

If you are not sure whether you should start using TRULICITY, talk to your doctor, pharmacist or diabetes nurse educator.

Check with your doctor if you:

- have any other medical conditions, especially pancreatitis (an inflamed pancreas causing severe stomach and back pain which does not go away), any condition affecting your digestive system or end stage kidney disease.
- If you have type 1 diabetes or diabetic ketoacidosis (often caused by very high blood sugar levels).
- if you have had an allergic reaction to any medicine which you have used previously to treat your current condition.
- if you are also taking a sulfonylurea (such as glimepiride or glibenclamide) or an insulin. Your doctor may tell you to test your blood sugar to decide if the dose of the sulfonylurea or insulin needs to be changed.
- take any medicines for any other condition

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

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Use of this medicine during pregnancy and breastfeeding has not been studied. It is not known whether taking TRULICITY may harm your unborn child, or if TRULICITY is excreted in significant amounts in breast milk.

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 may interfere with TRULICITY and affect how it works.

When TRULICITY is used with a medicine that contains sulfonylurea or insulin, low blood sugar (hypoglycaemia) can occur. The dose of your sulfonylurea or insulin may need to be reduced while you use TRULICITY.

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

4. How do I use TRULICITY?

Follow all directions given to you by your doctor, pharmacist or diabetes nurse educator carefully.

These may differ from the information contained in this leaflet.

How much to use

- The recommended dose of TRULICITY is 1.5 mg once weekly.

The dose is the amount contained in one single use pen.

Follow the instructions provided. Do not stop TRULICITY just because you feel better. It is important that you do not stop using TRULICITY unless your doctor tells you to do so.

When to use TRULICITY

- TRULICITY should be used once weekly, at any time of the day, with or without meals.
- You should take your TRULICITY **on the same day each week** if you can. To help you remember, you may wish to tick the day of the week when you take your first dose of TRULICITY on the box that your medicine comes in, or on a calendar.

How to use TRULICITY Pre-filled Pen (autoinjector)

- **Read the instructions for use for the pen carefully before using TRULICITY.**
- Inject TRULICITY under the skin of your stomach or upper leg.
- **You should inject the whole contents of the single use pen each week.**
- If the injection is given by someone else, it may be injected into your upper arm.

If you want to do so, you can use the same area of your body each week. But be sure to choose a different injection site within that area.

If you forget to use TRULICITY

TRULICITY should be used regularly on the same day each week. If you miss your dose on the usual day, and if there are at least 3 days before your next dose is due, then take your TRULICITY dose as soon as possible.

Take your next dose on your regular scheduled day.

If there are less than 3 days before your next dose is due, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for a forgotten dose.

- You can also change the day of the week when you take TRULICITY if needed, as long as it has been at least 3 days since your last dose of TRULICITY.
- If you have trouble remembering to use your medicine, ask your doctor, pharmacist, or diabetes nurse educator for some hints.

If you use too much TRULICITY

If you think that you have used too much TRULICITY, talk to your doctor immediately.

Too much TRULICITY can make you feel sick or be sick.

You should immediately:

- phone the Poisons Information Centre
(**by calling (Australia) 13 11 26 (New Zealand) 0800 764 766**), 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 TRULICITY?

Things you should do

While you are using TRULICITY, tell your doctor or pharmacist before you start any new medicine.

Remind any doctor, dentist, pharmacist or diabetes nurse educator you visit that you are using TRULICITY.

Tell your doctor, pharmacist or diabetes nurse educator if you are travelling.

- Ask your doctor for a letter explaining why you are taking injecting devices with you. Each country you visit will need to see this letter so you should take several copies.
- You may not be able to get TRULICITY in the country you are visiting. Your doctor, pharmacist or diabetes nurse educator can provide you with some helpful information.

If you become pregnant while using TRULICITY tell your doctor.

Always carry something to show you have diabetes.

Always carry glucose or sugary foods with you.

Call your doctor straight away if you:

- Experience low blood sugar (hypoglycaemia).
- When TRULICITY is used with a medicine that contains sulfonylurea or insulin, low blood sugar (hypoglycaemia) can occur. The dose of your sulfonylurea or insulin may need to be reduced while you use TRULICITY.

Things you should not do

- Do not stop using this medicine suddenly and without consulting your Doctor/Healthcare provider.
- Do not use the medicine if you think it has been frozen or exposed to excessive heat. It may not work as well.
- Do not give your TRULICITY to anyone else, even if they have the same condition as you. Your doctor has prescribed TRULICITY only for you.

Hypoglycaemia (low blood sugar)

- It is important you know and can recognise the symptoms of hypoglycaemia (low blood sugar).

Symptoms of mild to moderate low blood sugar (hypoglycaemia) can include:

- sweating
- hunger, headache
- tremor, unsteady movement
- light-headedness
- drowsiness, dizziness
- depressive mood, anxiety
- irritability, personality change
- abnormal behaviour
- inability to concentrate
- sleep disturbance
- blurred vision
- increased heart rate or irregular heartbeat
- tingling in the hands/feet/lips or tongue

- slurred speech.

Tell your doctor if you have trouble recognising the symptoms of hypoglycaemia.

Recognising these mild to moderate hypoglycaemic symptoms early may allow you to take the necessary steps to avoid more serious hypoglycaemia.

Symptoms of severe hypoglycaemia can include:

- disorientation
- seizures
- unconsciousness.

If you experience symptoms of low blood sugar, eat some sugary food or drink, such as jelly beans, orange juice or glucose tablets.

If you do not feel better after eating/drinking some sugary food or drink, contact your doctor or go to the Emergency Department at your nearest hospital

Tell your relatives, friends, close workmates or carers that you have Type 2 diabetes. It is important that they know and can recognise the signs and symptoms of hypoglycaemia.

Make sure they know to give you some sugary food or fruit juice for mild to moderate symptoms of hypoglycaemia.

If you lose consciousness, make sure they know:

- **to turn you on your side and get medical help immediately**
- **not to give you anything to eat or drink.**

Driving or using machines

Be careful before you drive or use any machines or tools until you know how TRULICITY affects you.

If you use TRULICITY in combination with sulfonylureas or insulin, low blood sugar (hypoglycaemia) can occur. Low blood sugar (hypoglycaemia) may reduce your ability to concentrate.

Drinking alcohol

Tell your doctor if you drink alcohol.

Alcohol may mask the symptoms of low blood sugar (hypoglycaemia), or make it worse.

Looking after your medicine

- **Keep TRULICITY pens in a fridge between 2°C - 8°C.**
- When refrigeration is not possible, you can keep your pen at room temperature (below 30°C) for up to a total of 14 days.
- **Do not allow the pen to freeze. Do not use it if it has been frozen.**
- Keep TRULICITY in the original package in order to protect it from light.
- Do not use a pen after the expiry date (month, year) stamped on the label.

Follow the instructions in the carton on how to take care of your medicine properly.

Keep it where young children cannot reach it.

When to discard your medicine

If your doctor tells you to stop using TRULICITY.

Empty pens should be disposed of in a sharps container or similar puncture proof container composed of hard plastic or glass.

Ask your doctor, pharmacist, or diabetes nurse educator where you can dispose of the container once it is full.

You can also refer to the instructions for use for the pen for additional information on storage and handling of this medicine.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

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.

Less serious side effects

Less serious side effects	What to do
<p>Stomach complaints:</p> <ul style="list-style-type: none">• Feeling sick (nausea)• Diarrhoea• vomiting• Abdominal (stomach) pain (also refer to Serious Side Effects)• Heartburn, indigestion• Constipation• Increased burping, belching or farting (flatulence)• Bloating• Indigestion (reflux)• Decreased appetite• Difficulty swallowing <p>General disorders and Injection site related:</p> <ul style="list-style-type: none">• Tiredness, loss of energy and strength• Redness, swelling or itching at the injection site	<p>Speak to your doctor if you have any of these less serious side effects and they persist or worry you.</p>

Serious side effects

Serious side effects	What to do
<p>Metabolism and nutrition related:</p> <ul style="list-style-type: none"> • Symptoms of dehydration (such as dry mouth, decreased frequency of urination and concentrated urine, headache, muscle weakness, dizziness or light headedness.) • Symptoms of severe low blood sugar (disorientation, seizures, fits or convulsions, loss of consciousness) <p>Stomach complaints:</p> <ul style="list-style-type: none"> • Symptoms of acute pancreatitis (severe pain in the stomach and back which does not go away, vomiting, diarrhoea) <p>Gallbladder complaints:</p> <ul style="list-style-type: none"> • Gallstones or an inflamed gallbladder (symptoms may include pain in your upper 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Serious side effects	What to do
<p>stomach (abdomen), fever, yellowing of skin or eyes (jaundice), clay-coloured stools)</p> <p>Severe allergic reactions:</p> <p>You should see a doctor immediately if you experience symptoms of an allergic reaction such as;</p> <ul style="list-style-type: none"> • rashes • itching and rapid swelling of the tissues of the neck, face, mouth, or throat • hives, and • difficulty breathing 	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

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 TRULICITY contains

Active ingredient (main ingredient)	dulaglutide (rch)
Other ingredients (inactive ingredients)	sodium citrate dihydrate citric acid mannitol polysorbate 80 Water for Injections

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

What TRULICITY looks like

TRULICITY is a clear colourless solution available as a single use pre-filled pen (autoinjector).

TRULICITY is available:

Australia:

TRULICITY 1.5 mg/0.5 mL Pre-filled Pen
(Autoinjector). AUST R 217965

New Zealand:

TRULICITY 1.5 mg/0.5 mL Pre-filled Pen
(Autoinjector). TT50-10823

Who distributes TRULICITY

Australia:

Eli Lilly Australia Pty Ltd
Level 9, 60 Margaret Street
SYDNEY NSW 2000

New Zealand:

Eli Lilly and Company (NZ) Limited
PO Box 109 197
Newmarket Auckland 1149

Further Information

You can get more information about diabetes from:

Diabetes Australia

- freecall helpline 1300 136 588
- www.diabetesaustralia.com.au.

Diabetes New Zealand

- freecall helpline 0800 DIABETES (0800 342 238)
- www.diabetes.org.nz

If you have any questions about TRULICITY, contact Lilly at 1800 454 559 (Australia), or 0800 500 056 (New Zealand) or your healthcare professional for assistance.

To check for CMI updates and obtain the latest version, visit:

- Australia: www.ebs.tga.gov.au
- New Zealand: www.medsafe.govt.nz

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