

TRULICITY[®]

Single dose Prefilled Pen (autoinjector)

Dulaglutide (rch)

Consumer Medicine Information

What is in this leaflet

This leaflet is designed to provide you with answers to some common questions about this medicine.

It does not contain all the available information and does not take the place of talking with your doctor.

The information in this leaflet was last updated on the date shown on the final page. More recent information on this medicine may be available. Make sure you speak to your pharmacist, nurse or doctor to obtain the most up to date information on this medicine. You can also download the most up to date leaflet from www.lilly.com.au. The updated leaflet may contain important information about TRULICITY and its use of which you should be aware.

All medicines have risks and benefits. Your doctor has more information about this medicine than is contained in this leaflet. Also, your doctor has had the benefit of taking a full and detailed history from you and is in the best position to make an expert judgement to meet your individual needs.

If you have any concerns about using this medicine, talk to your doctor or pharmacist.

Keep this leaflet with your medicine.

You may need to read it again.

What TRULICITY is used for

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.

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.

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.

This medicine is available only with a doctor's prescription.

Ask your doctor, diabetes nurse or pharmacist if you have any questions about why this medicine has been prescribed for you.

Before you use TRULICITY

Tell your doctor if you have any of the following conditions or if you have ever experienced any of these conditions.

When you must not use TRULICITY

Do not use/inject TRULICITY:

- **if you have had an allergy to any medicine containing dulaglutide, or to any of the ingredients listed at the end of this leaflet (see 'Product Description').**

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).**
- **if the product appears cloudy, discoloured or contains particles.**
- **if the expiry date on the pack has passed.**

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

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

Before you start to use TRULICITY

You must tell your doctor:

- if you have had an allergic reaction to any medicine which you have used previously to treat your current condition.
- If you have type 1 diabetes or diabetic ketoacidosis (often caused by very high blood sugar levels).
- if you have or have had any 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 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.

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

Use of this medicine during pregnancy has not been studied. It is not known whether taking TRULICITY may harm your unborn child.

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

It is not known if TRULICITY is excreted in significant amounts in breast milk.

Tell your doctor about these things before you use TRULICITY.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

How to use TRULICITY

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

These may differ from the information contained in this leaflet.

If you do not understand the instructions, ask your doctor, diabetes nurse or pharmacist for help.

How much to use

The recommended dose of TRULICITY is 1.5 mg once a week.

This is the amount contained in one single use pen.

You should inject the whole contents of the single use pen each week.

When to use TRULICITY

TRULICITY should be used once a week, 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 it

Inject TRULICITY under the skin of your stomach or upper leg.

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.

Read the instructions for use for the pen carefully before using TRULICITY.

How long do I use it

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.

If you use too much

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

If you use too much TRULICITY, talk to your doctor immediately or contact:

In Australia: Poisons Information Centre on 13 11 26

In NZ: National Poisons Centre on 0800 POISON or 0800 764 766

If you miss a dose

If you forget to use your TRULICITY, and if there are at least 3 days before your next dose is due, then take your TRULICITY 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 and take the next one on your regular scheduled day.

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

You can also change the day of the week on which you take TRULICITY if necessary, 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 for some hints.

While you are using TRULICITY

Things you must do

Tell all doctors, dentists and pharmacists who are treating you that you are using TRULICITY.

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

Tell your doctor, diabetes nurse or pharmacist 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, diabetes nurse or pharmacist 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.

Tell your doctor if you experience hypoglycaemia (low blood sugar).

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

Symptoms of mild to moderate 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 heart beat
- tingling in the hands/feet/lips or tongue
- slurred speech.

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.

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

What to do if you have hypoglycaemia

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 diabetes. It is important that they 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.**

Things you must not do

Do not stop using TRULICITY without first checking with your doctor.

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 specifically for you.

Things to be careful of

Tell your doctor if you drink alcohol.

Alcohol may mask the symptoms of hypoglycaemia, or make it worse.

Be careful driving or operating machinery.

If you use TRULICITY in combination with sulfonylureas or insulin, hypoglycaemia can occur. Hypoglycaemia may reduce your ability to concentrate.

Side effects

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

Like other medicines, TRULICITY may cause some unwanted side effects. These are likely to vary from patient to patient.

Tell your doctor as soon as possible about any unwanted effects.

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.

Ask your doctor or pharmacist to answer any questions you may have.

When TRULICITY is used with a medicine that contains sulfonylurea or insulin, hypoglycaemia can occur.

Tell your doctor if you experience hypoglycaemia.

Tell your doctor if you experience any of the following side effects:

- nausea
- diarrhoea
- vomiting
- stomach pain or distension or bloating
- heartburn
- difficulty swallowing
- loss of appetite

- constipation
- increased burping or flatulence
- tiredness, loss of energy and strength
- redness, swelling or itching at the injection site

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

Nausea, diarrhoea and vomiting were very commonly reported in patients using TRULICITY. Mostly these were mild to moderate and short-lived. Most patients experienced these side effects worst in the first 2 weeks of starting treatment followed by rapid improvement over the next 4 weeks.

You may experience dehydration as a result of nausea, vomiting and/or diarrhoea, which may lead to a decrease in kidney function. Some symptoms of mild to moderate dehydration include:

- dry mouth
- decreased frequency of urination and concentrated urine
- headache
- muscle weakness
- dizziness or light headedness.

Drink plenty of fluids if you are experiencing any of these symptoms. Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you continue to experience these symptoms.

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you experience signs of severe hypoglycaemia:

- disorientation
- seizures, fits or convulsions
- loss of consciousness.

Tell your doctor immediately if you experience symptoms of acute pancreatitis:

- severe abdominal pain and

- vomiting and/or
- diarrhoea and/or
- nausea.

Pancreatitis is a serious condition that has been reported rarely with other medicines similar to TRULICITY.

Do not be alarmed at this list of side effects.

You may not experience any of them.

Tell your doctor if you notice anything unusual or if you are concerned about any aspect of your health, even if you think the problems are not connected with this medicine and are not referred to in this leaflet.

Other side effects not listed above may also occur in some people.

After using TRULICITY

Storage

Keep your 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.

All medicines should be kept where young children cannot reach them.

Disposal

If your doctor tells you to stop using TRULICITY or you find your pens have passed their expiry date, please return them to your pharmacist.

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

Ask your doctor, diabetes nurse or pharmacist 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.

Product Description

What it looks like

TRULICITY is a clear colourless solution available as a single use pen.

Ingredients

Active Ingredient:

- dulaglutide (1.5 mg)

Inactive Ingredients:

- sodium citrate dihydrate
- citric acid
- mannitol
- polysorbate 80
- water for injections

Supplier

Supplied in Australia by:

Eli Lilly Australia Pty Limited
112 Wharf Road
WEST RYDE NSW 2114
AUSTRALIA

Supplied in New Zealand by:

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

Registration Number(s):

Australia: AUST R 217965

Further Information

Diabetes Australia – for further information about diabetes

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

Diabetes New Zealand – for further information about diabetes

- freecall helpline 0800
DIABETES (0800 342 238)

www.diabetes.org.nz

Eli Lilly – if you have any questions about TRULICITY, contact Lilly at

- 1800 454 559 (Australia),
- 0800 500 056 (NZ)

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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