

Package leaflet: Information for the patient

Trulicity® 0.75 mg solution for injection in pre-filled pen Trulicity® 1.5 mg solution for injection in pre-filled pen dulaglutide

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Trulicity is and what it is used for
2. What you need to know before you use Trulicity
3. How to use Trulicity
4. Possible side effects
5. How to store Trulicity
6. Contents of the pack and other information

1. What Trulicity is and what it is used for

Trulicity contains an active substance called dulaglutide and is used to lower blood sugar (glucose) in adults with type 2 diabetes mellitus.

Type 2 diabetes is a condition in which your body does not make enough insulin, and the insulin that your body produces does not work as well as it should. Your body can also make too much sugar. When this happens, sugar (glucose) builds up in the blood.

Trulicity is used:

- on its own if your blood sugar is not properly controlled by diet and exercise alone, and you can't take metformin (another diabetes medicine).
- or with other medicines for diabetes when they are not enough to control your blood sugar levels. These other medicines may be medicines taken by mouth and/or insulin given by injection.

It is important to continue to follow the advice on diet and exercise given to you by your doctor, pharmacist or nurse.

2. What you need to know before you use Trulicity

Do not use Trulicity

- if you are allergic to dulaglutide or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Trulicity if:

- you are on dialysis as this medicine is not recommended.
- you have type 1 diabetes (the type that usually starts when you are young and your body does not produce any insulin) as this medicine may not be right for you.
- you have diabetic ketoacidosis (a complication of diabetes that occurs when the body is unable to break down glucose because there is not enough insulin). The signs include rapid weight loss, feeling sick or being sick, a sweet smell to your breath, a sweet or metallic taste in your mouth, or a different odour to your urine or sweat.
- you have severe problems with food digestion or food remaining in your stomach for longer than normal (including gastroparesis).
- you have ever had pancreatitis (inflammation of the pancreas) which causes severe pain in the stomach and back which does not go away.
- you are taking a sulphonylurea or insulin for your diabetes, as low blood sugar (hypoglycaemia) can occur. Your doctor may need to change your dose of these other medicines to reduce this risk.

Trulicity is not an insulin and should therefore not be used as a substitute for insulin.

When initiating treatment with Trulicity, you may in some cases experience loss of fluids/dehydration, e.g. in case of vomiting, nausea and/or diarrhoea which may lead to a decrease in kidney function. It is important to avoid dehydration by drinking plenty of fluids. Contact your doctor if you have any questions or concerns.

Children and adolescents

Trulicity is not recommended for children and adolescents under 18 years of age because it has not been studied in these patients.

Other medicines and Trulicity

Tell your doctor, pharmacist or nurse if you are using, have recently used or might use any other medicine.

Especially tell your doctor:

- if you are using other medicines that lower the amount of sugar in your blood, such as insulin or a medicine containing sulphonylurea. Your doctor may want to lower the dose of these other medicines to prevent you from getting low blood sugar levels (hypoglycaemia). Ask your doctor, pharmacist or nurse if you are not sure what your other medicines contain.
- if you are using insulin, your doctor will tell you how to reduce the dose of insulin and will recommend you to monitor your blood sugar more frequently, in order to avoid hyperglycaemia (high blood sugar) and diabetic ketoacidosis (a complication of diabetes that occurs when the body is unable to break down glucose because there is not enough insulin).

Pregnancy and breast-feeding

It is not known if dulaglutide could harm your unborn child. Women who could become pregnant should use contraception during treatment with dulaglutide. Tell your doctor if you are pregnant, think you may be pregnant or are planning to have a baby, as Trulicity should not be used during pregnancy. Talk to your doctor about the best way to control your blood sugar while you are pregnant.

Talk to your doctor if you would like to or are breast-feeding before taking this medicine. Do not use Trulicity if you are breast-feeding. It is not known if dulaglutide passes into human breast milk.

Driving and using machines

If you use Trulicity in combination with a sulphonylurea or insulin, low blood sugar (hypoglycaemia) may occur which may reduce your ability to concentrate. Please keep this in mind in all situations where you might put yourself and others at risk (e.g. driving a car or using machines).

Trulicity contains sodium citrate

This medicine contains less than 1 mmol sodium (23 mg) per 0.75 mg or 1.5 mg, that is to say essentially ‘sodium-free’.

3. How to use Trulicity

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure how to use this medicine.

When used alone, the recommended dose is 0.75 mg once a week.

When used with other medicines for diabetes, the recommended dose is 1.5 mg once a week. In certain situations, for example if you are 75 years or older, your doctor may recommend a starting dose of 0.75 mg once a week.

Each pen contains one weekly dose of Trulicity (0.75 mg or 1.5 mg). Each pen delivers only one dose.

You can use your Trulicity at any time of the day, with or without meals. You should use it 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 inject your first dose on the box that your Trulicity comes in, or on a calendar.

Trulicity is injected under the skin (subcutaneous injection) of your stomach area (abdomen) or upper leg (thigh). If the injection is given by someone else, they may inject in 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.

It is important that you test your blood glucose levels as instructed by your doctor, pharmacist or nurse, if you are taking Trulicity with a sulphonylurea or insulin.

Read the “Instructions for Use” for the pen carefully before using Trulicity.

If you use more Trulicity than you should

If you use more Trulicity than you should talk to your doctor immediately. Too much Trulicity may make your blood sugar too low (hypoglycaemia) and can make you feel sick or be sick.

If you forget to use Trulicity

If you forget to inject a dose, and if there are **at least 3 days** before your next dose is due, then inject your dose as soon as possible. Inject 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 inject the next one on your regular scheduled day.

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

You can also change the day of the week on which you inject Trulicity if necessary, as long as it has been at least 3 days since your last dose of Trulicity.

If you stop using Trulicity

Do not stop using Trulicity without talking with your doctor. If you stop using Trulicity, your blood sugar levels can increase.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Severe allergic reactions (anaphylactic reactions) have been reported rarely (may affect up to 1 in 1,000 people).

You should see a doctor immediately if you experience symptoms such as:

- Rashes, itching and rapid swelling of the tissues of the neck, face, mouth or throat
- Hives and difficulties breathing.

Very common side effects with dulaglutide that may affect more than 1 in 10 people using this medicine are:

- Nausea (feeling sick)
- Vomiting (being sick)
- Diarrhoea
- Abdominal (stomach) pain.

These side effects are usually not severe. They are most common when first starting dulaglutide but decrease over time in most patients.

Hypoglycaemia (low blood sugar) is very common when dulaglutide is used with medicines that contain metformin, a sulphonylurea and/or insulin. If you are taking a sulphonylurea or insulin, the dose may need to be lowered while you use dulaglutide.

Hypoglycaemia is common (may affect up to 1 in 10 people using this medicine) when dulaglutide is used alone, or with both metformin and pioglitazone together, or with a sodium-glucose co-transporter 2 inhibitor (SGLT2i) with or without metformin.

Symptoms of low blood sugar may include headache, drowsiness, weakness, dizziness, feeling hungry, confusion, irritability, fast heartbeat and sweating. Your doctor should tell you how to treat low blood sugar.

Other common side effects:

- Feeling less hungry (decreased appetite)
- Indigestion
- Constipation
- Gas (flatulence)
- Bloating of the stomach
- Gastroesophageal reflux disease - a disease caused by stomach acid coming up into the tube from your stomach to your mouth
- Burping
- Feeling tired
- Increased heart rate
- Slowing of the electrical currents in the heart

Uncommon side effects (may affect up to 1 in 100 people using this medicine):

- Injection site reactions (e.g. rash or redness)
- Whole body allergic reactions (hypersensitivity) (e.g. swelling, raised itchy skin rash (hives))
- Dehydration, often associated with nausea, vomiting and/or diarrhoea
- Gallstones
- Inflamed gallbladder

Rare side effects (may affect up to 1 in 1,000 people using this medicine):

- Inflamed pancreas (acute pancreatitis)

The following side effect has been reported but the frequency for it to occur is not known:

- Bowel obstruction - a severe form of constipation with additional symptoms such as stomach ache, bloating or vomiting

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via **Ireland:** HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2, Tel: +353 1 6764971, Fax: +353 1 6762517, Website: www.hpra.ie, e-mail: medsafety@hpra.ie, **Malta:** ADR Reporting, Website: www.medicinesauthority.gov.mt/adrportal, **United Kingdom:** Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Trulicity

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the pen label and on the carton after EXP.

The expiry date refers to the last day of that month.

Store in a refrigerator (2°C - 8°C). Do not freeze.

Store in the original packaging in order to protect from light.

Trulicity can be taken out of the fridge for up to 14 days at a temperature not above 30°C.

Do not use this medicine if you notice that the pen is damaged, or the medicine is cloudy, discoloured or has particles in it.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Trulicity contains

The active substance is dulaglutide.

- *Trulicity 0.75 mg*: Each pre-filled pen contains 0.75 mg of dulaglutide in 0.5 ml solution.
- *Trulicity 1.5 mg*: Each pre-filled pen contains 1.5 mg of dulaglutide in 0.5 ml solution.

The other ingredients are sodium citrate; citric acid, anhydrous; mannitol; polysorbate 80 and water for injections.

What Trulicity looks like and contents of the pack

Trulicity is a clear, colourless, solution for injection (injection) in a pre-filled pen.

Each pre-filled pen contains 0.5 ml solution.

The pre-filled pen is for single-use only.

Pack sizes of 2, 4 or multipacks of 12 (3 packs of 4) pre-filled pens. Not all pack sizes may be available in your country.

Marketing Authorisation Holder

Eli Lilly Nederland B.V., Papendorpseweg 83, 3528 BJ Utrecht, The Netherlands.

Manufacturer

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Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site:

<http://www.ema.europa.eu>.