

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
Trulicity® 3 mg solution for injection in pre-filled pen
Trulicity® 4.5 mg solution for injection in pre-filled pen
dulaglutide

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 and children aged 10 years and above, with type 2 diabetes mellitus and can help prevent heart disease.

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.

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 when 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.

Symptoms, sometimes severe, of delayed emptying of stomach contents such as feeling of fullness, nausea and/or vomiting have been reported in patients using Trulicity. Tell your doctor if you develop severe problems with your stomach emptying that will not go away while using Trulicity.

If you know that you are due to have surgery where you will be under anaesthesia (sleeping), please tell your doctor that you are taking Trulicity.

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 can be used in children and adolescents aged 10 years and above. Data is not available in children below 10 years of age.

Other medicines and Trulicity

Because Trulicity can slow stomach emptying which could affect other medicines, tell your doctor, pharmacist or nurse if you are using, have recently used or might use any other medicine.

Pregnancy

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.

Breast-feeding

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

Trulicity has no to little effect on the ability to drive or use machines. However, if you use Trulicity in combination with a sulphonylurea or insulin, low blood sugar (hypoglycaemia) may occur which may reduce your ability to concentrate. Avoid driving or using machines if you get any signs of low blood sugar. See section 2, 'Warning and precautions' for information on increased risk of low blood sugar and section 4 for the warning signs of low blood sugar. Talk to your doctor for further information.

Trulicity contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per dose, 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.

Adults

Your doctor may recommend a dose of 0.75 mg once a week for the treatment of your diabetes when Trulicity is used alone.

When used with other medicines for diabetes, your doctor may recommend a dose of 1.5 mg once a week.

If your blood sugar is not controlled well enough, your doctor may increase your dose to 3 mg once a week.

If further blood sugar control is needed the dose may be increased again to 4.5 mg once a week.

Children and adolescents

The starting dose for children and adolescents aged 10 years and above is 0.75 mg once a week. If your blood sugar is not controlled well enough after at least 4 weeks, your doctor may increase your dose to 1.5 mg once a week.

Each pen contains one weekly dose of Trulicity (0.75 mg, 1.5 mg, 3 mg or 4.5 mg). Each pen delivers only one dose.

You can use your pen 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 pen 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 of this medicine 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 side effects

Rare: may affect up to 1 in 1,000 people

- Severe allergic reactions (anaphylactic reactions, angioedema).
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.
- Inflamed pancreas (acute pancreatitis) which could cause severe pain in the stomach and back which does not go away.
You should see a doctor immediately if you experience such symptoms.

Not known: the frequency cannot be estimated from the available data

- Bowel obstruction - a severe form of constipation with additional symptoms such as stomach ache, bloating or vomiting.
You should see a doctor immediately if you experience such symptoms.

Other side effects

Very common: may affect more than 1 in 10 people

- Feeling sick (nausea) – this usually goes away over time
- Being sick (vomiting) – this usually goes away over time
- Diarrhoea – this usually goes away over time
- Stomach (abdominal) pain.

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

- Low blood sugar (hypoglycaemia) 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.
- 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.

Common: may affect up to 1 in 10 people

- Low blood sugar (hypoglycaemia) is common 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. For a list of possible symptoms, see above under very common affects.
- Feeling less hungry (decreased appetite)
- Indigestion
- Constipation
- Gas (flatulence)
- Bloating of the stomach
- Reflux or heartburn (also called gastroesophageal reflux disease – GERD) - 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: may affect up to 1 in 100 people

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

Rare: may affect up to 1 in 1,000 people

- A delay in the emptying of the stomach

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 the 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.
- *Trulicity 3 mg*: Each pre-filled pen contains 3 mg of dulaglutide in 0.5 ml solution.
- *Trulicity 4.5 mg*: Each pre-filled pen contains 4.5 mg of dulaglutide in 0.5 ml solution.

The other ingredients are sodium citrate (see section 2 under ‘Trulicity contains sodium’ for further information); citric acid; mannitol; polysorbate 80 and water for injections.

What Trulicity looks like and contents of the pack

Trulicity is a clear, colourless, solution for 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

For 0.75 mg and 1.5 mg: Lilly France, 2, rue du Colonel Lilly, 67640 Fegersheim, France

For 3 mg and 4.5 mg only: Eli Lilly Italia S.p.A., Via Gramsci 731/733, 50019, Sesto Fiorentino, Firenze (FI), Italy

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

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