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Package leaflet: Information for the patient

Trulicity® 3 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

The name of your medicine is Trulicity 3 mg solution for injection in pre-filled pen but will be referred to as Trulicity throughout this leaflet.

Please note that the leaflet also contains information about other strengths.

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; see section 4).
- 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 anesthesia (sleeping), please tell your doctor that you are using 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 dulagutide. 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. This is a serious, potentially life-threatening condition.
  You should see a doctor immediately if you experience such symptoms.

Stop using this medicine and seek urgent medical help if you experience:
– Severe, persistent pain in the stomach area (abdomen), with or without nausea and vomiting. This could be a sign of acute pancreatitis, which is serious and potentially life-threatening.

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
– Change in the way food or drink tastes

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 at: 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 30ºC.

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

If this medicine becomes discoloured or shows any other signs of deterioration, please contact your pharmacist who will advise you on what to do.

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 3 mg:* Each pre-filled pen contains 3 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 size of 4 pre-filled pens.

Product Licence Holder and Manufacturer
Procured from within the EU by the Product Licence holder Orifarm UK Ltd.,
Ground Floor Suite A2, Breakspear Park, Breakspear Way, Hemel Hempstead, HP2 4TZ, UK

For any information about this medicine, please contact the Product Licence Holder on
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Manufactured by
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Trulicity 3 mg solution for injection in pre-filled pen
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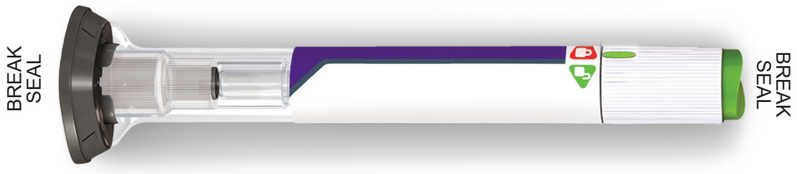
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Leaflet revision date: 04/11/2025

Blind or partially sighted?
Is this leaflet hard to see or read?
Call +45 63 95 27 00
to obtain the leaflet in a format suitable for you.

INSTRUCTIONS FOR USE

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



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ABOUT TRULICITY PRE-FILLED PEN

Please read these instructions for use and the information for the patient in the package leaflet carefully and completely before using your pre-filled pen. Talk to your doctor, pharmacist or nurse about how to inject Trulicity correctly.

- The pen is a disposable, pre-filled delivery device that is ready to use. Each pen contains one weekly dose of Trulicity (3 mg). Each pen delivers one dose only.
- **Trulicity is administered once a week.** You may want to mark your calendar to remind you when to inject your next dose.
- When you press the green injection button, the pen will automatically insert the needle **into your skin,** inject the medicine, and pull back (retract) the needle **after the injection is complete.**

BEFORE YOU GET STARTED

Remove
from the refrigerator.

Leave the base cap on until you are ready to inject.

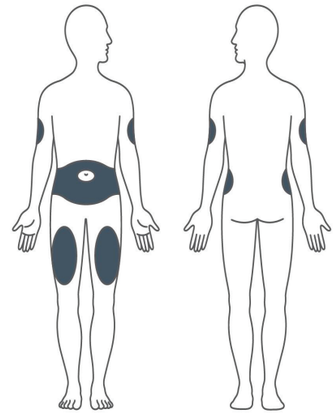
Check
the label to make sure you have the correct medicine and it has not expired.

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

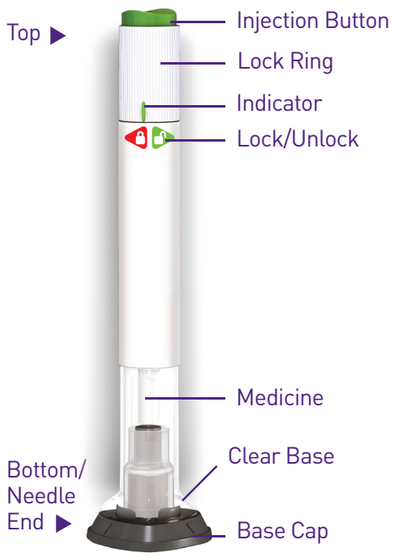
Prepare
by washing your hands.

CHOOSE YOUR INJECTION SITE

- Your doctor, pharmacist or nurse can help you choose the injection site that is best for you.
- You may inject the medicine into your stomach (abdomen) or thigh.
- Another person may give you the injection in your upper arm.
- Change (rotate) your injection site each week. You may use the same area of your body, but be sure to choose a different injection site in that area.

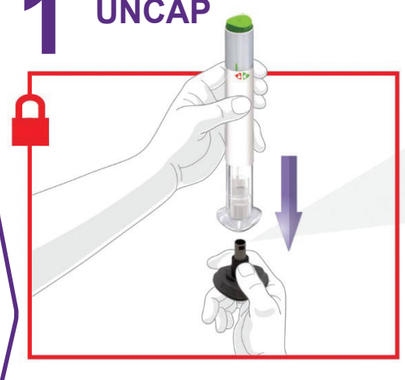


1. UNCAP
2. PLACE AND UNLOCK
3. PRESS AND HOLD



CONTINUED ON BACK

1 UNCAP





If the grey base cap does not look like the image above:

- **Do not** use the Pen.
- Safely store the Pen and cap and contact Lilly.
- Use a new Pen.

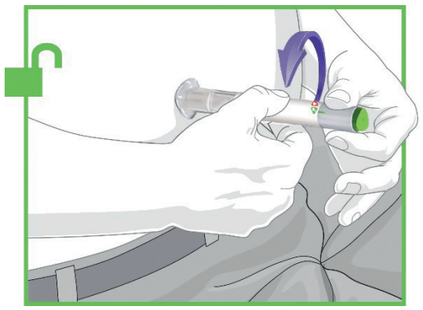
Make sure the pen is **locked**

- Pull off the grey base cap.

Do not put the base cap back on – this could damage the needle. Do not touch the needle.

- When removed, the grey base cap appears as shown and can be discarded.

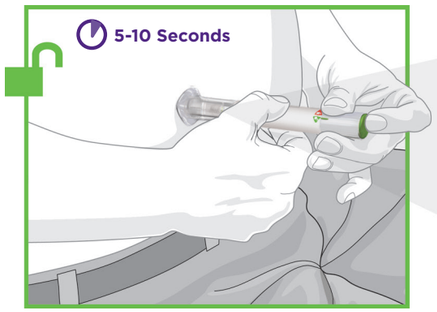
2 PLACE AND UNLOCK



- Place the clear base flat and firmly against your skin at the injection site.

Unlock by turning the lock ring.

3 PRESS AND HOLD





- **You will know your injection is complete when the grey part is visible.**

- Press and hold the green injection button; you will hear a loud click.
- ⚠ Continue holding the clear base firmly against your skin until you hear a second click. This occurs when the needle starts retracting in about 5-10 seconds.
- Remove the pen from your skin.

IMPORTANT INFORMATION

Storage and Handling

Disposal of Pen

Commonly Asked Questions

Other Information

Where to Learn More

STORAGE AND HANDLING

- The pen contains glass parts. Handle it carefully. If you drop it on a hard surface, do not use it. Use a new pen for your injection.
- Store your pen in the refrigerator.
- 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 freeze your pen. If the pen has been frozen, DO NOT USE.
- Store the pen in the original package in order to protect from light.
- Keep the pen out of sight and reach of children.
- For complete information about proper storage, read the Information for the patient.

DISPOSAL OF PEN

- Dispose of the pen in a sharps container or as directed by your doctor, pharmacist or nurse.
- Do not recycle the filled sharps container.
- Ask your doctor, pharmacist or nurse about how to dispose of medicines you no longer use.



COMMONLY ASKED QUESTIONS

What if I see an air bubble in my pen?
Air bubbles are normal. They will not harm you or affect your dose.

What if I unlock the pen and press the green injection button before pulling off the base cap?
Do not remove the base cap and do not use the pen. Dispose of the pen as directed by your doctor, pharmacist or nurse. Inject your dose using another pen.

What if there is a drop of liquid on the tip of the needle when I remove the base cap?
A drop of liquid on the tip of the needle is not unusual and will not affect your dose.

Do I need to hold the injection button down until the injection is complete?
This is not necessary, but it may help you keep the pen steady and firm against your skin.

I heard more than two clicks during my injection - two louder clicks and a soft one. Did I get my complete injection?
Some patients may hear a soft click right before the second loud click. That is the normal operation of the pen. Do not remove the pen from your skin until you hear the second louder click.

What if there is a drop of liquid or blood on my skin after my injection?
This is not unusual and will not affect your dose.

I'm not sure my pen worked correctly.
Check to see if you have received your dose. Your dose was delivered correctly if the grey part is visible (see step 3). Also contact your local Lilly office listed in the Information for the patient for further instructions. Until then, store your pen safely to avoid an accidental needle stick injury.

OTHER INFORMATION

- If you have vision problems, DO NOT use your pen without help from a person trained to use the Trulicity pen.

WHERE TO LEARN MORE

- If you have any questions or problems with your Trulicity pen, contact your doctor, pharmacist or nurse.

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