

**PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS
(PREPARATIONS) - 1986**

This medicine is dispensed with a physician's prescription only

**Trulicity 0.75 mg,
Solution for injection in
a pre-filled pen**

Active ingredient and its concentration:
Each pre-filled pen contains:
0.75 mg dulaglutide in 0.5 ml solution

**Trulicity 1.5 mg,
Solution for injection in
a pre-filled pen**

Active ingredient and its concentration:
Each pre-filled pen contains:
1.5 mg dulaglutide in 0.5 ml solution

Inactive ingredients and allergens in the preparation: See chapter 2 section "Important information about some of the ingredients of this medicine" and chapter 6 "Additional information".

Read the entire leaflet carefully before using this medicine. This leaflet contains concise information about the medicine. If you have any further questions, ask your doctor or pharmacist.

This medicine has been prescribed for the treatment of your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness is the same as yours.

1. WHAT IS THIS MEDICINE USED FOR?

Trulicity is indicated for the treatment of adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise:

- as monotherapy when metformin is considered inappropriate due to intolerance or contraindications.
- in addition to other medicinal products for the treatment of diabetes

Therapeutic group: Drugs used in diabetes, blood glucose lowering drugs, excluding insulins.

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

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

2. BEFORE USING THIS MEDICINE

Do not use this medicine if:

- you are allergic (hypersensitive) to the active ingredient (dulaglutide) or to any of the other ingredients of this medicine (listed in chapter 6).

Special warnings regarding the use of this medicine

Before starting treatment with Trulicity, tell your doctor if:

- you are on dialysis as this medicine is not recommended in this condition.
- 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 odor 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 (hypoglycemia) can occur. Your doctor may need to change your dose of these other medicines to reduce this risk.

Trulicity is not a medicine that contains 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 diarrhea 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.

Drug interactions

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including non-prescription drugs and nutritional supplements, because **Trulicity** can slow stomach emptying which could affect other medicines.

Use of this medicine and food

You may take **Trulicity** with or without meals.

Pregnancy, breastfeeding and fertility

Pregnancy

It is not known if dulaglutide could harm your unborn child. Women of child-bearing age 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.

Breastfeeding

Talk to your doctor if you would like to or are breastfeeding before taking this medicine. Do not use **Trulicity** if you are breastfeeding. It is not known if dulaglutide passes into 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 (hypoglycemia) may occur which may reduce your ability to concentrate. Avoid driving or using machines if you get any signs of low blood sugar. See chapter 2, under section “Special warnings regarding the use of this medicine” for information on increased risk of low blood sugar and chapter 4 “Side effects” for the warning signs of low blood sugar. Talk to your doctor for further information.

Important information about some of the ingredients of this medicine

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

3. HOW TO USE THIS MEDICINE?

The medicine should always be used according to the doctor's instructions. You should check with your doctor or pharmacist if you are not sure about the dosage and manner of treatment with this medicine.

The dosage and manner of treatment will be determined only by the doctor.

The usual dose is:

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

When used with other medicines for diabetes, the usual dose is 1.5 mg once a week.

Do not exceed the recommended dose.

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 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 of the pen, 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 inject in 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 have accidentally taken a higher dose

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 (hypoglycemia) and can make you feel sick or be sick. If you have accidentally taken a higher dose or if a child has accidentally injected the medicine, proceed immediately to a doctor or a hospital Emergency Room and bring the package of the medicine with you.

If you forget to take this medicine

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 forgotten 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**.

Continue with the treatment as recommended by your doctor.

Even if there is an improvement in your health, do not stop treatment with this medicine without consulting your doctor.

If you stop taking this medicine

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

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

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

4. SIDE EFFECTS

Like all medicines, the use of **Trulicity** can cause side effects in some users. Do not be alarmed while reading the list of side effects. You may not suffer from any of them.

Severe side effects

Rare side effects (may affect up to 1 in 1,000 users):

- 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 side effects (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 side effects (may affect more than 1 in 10 users):

- Feeling sick (nausea) - this usually goes away over time
- Being sick (vomiting) - this usually goes away over time
- Diarrhea - 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 (hypoglycemia) is very common when dulaglutide is used with other 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 using 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 side effects (may affect up to 1 in 10 users):

- Low blood sugar (hypoglycemia) 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 side effects.
- 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 side effects (may affect up to 1 in 100 users):

- 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 diarrhea
- Gallstones
- Inflamed gallbladder
- Change in the way food or drink tastes

Rare side effects (may affect up to 1 in 1,000 users):

- A delay in the emptying of the stomach

If any of the side effects appears, if any of the side effects gets worse or if you experience a side effect not listed in this leaflet, you should consult with your doctor.

Reporting side effects

Side effects can be reported to the Ministry of Health by clicking on the link “Reporting side effects due to drug treatment’ that can be found on the Home Page of the Ministry of Health’s website (www.health.gov.il), which refers to an online form for reporting side effects, or by entering the following link:

<https://sideeffects.health.gov.il>

5. HOW TO STORE THIS MEDICINE?

Avoid poisoning! This medicine and all other medicines must be stored in a closed place out of the reach and sight of children and/or infants to avoid poisoning.

Do not use this medicine after the expiry date (exp. date) which is stated on the pen label and on the carton. The expiry date refers to the last day of that month.

Storage conditions:

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

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

During use, **Trulicity** may be stored unrefrigerated for up to 14 days at a temperature below 30°C. If the pen has been left out of the refrigerator for more than 14 days, the pen must be discarded even if it has not reached the expiration date.

Do not use this medicine if you notice that the pen is damaged, or the medicine is cloudy, discolored 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. ADDITIONAL INFORMATION

In addition to the active ingredient, this medicine also contains:

mannitol, trisodium citrate dihydrate, polysorbate 80, citric acid anhydrous, water for injection.

What the medicine looks like and contents of the pack:

Trulicity is a clear, colorless, 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.

Each pack contains 4 pre-filled pens.

Registration holder’s name and address: Eli Lilly Israel Ltd., 4 HaSheizaf St., P.O.Box 4246, Ra'anana 4366411

Manufacturer’s name and address: Eli Lilly and Company, Lilly Corporate Center, Indianapolis, Indiana (IN) 46285, USA.

Revised in August 2025.

Drug registration numbers at the national medicine’s registry of the Ministry of Health:

Trulicity 0.75 mg: 154-39-34356-00

Trulicity 1.5 mg: 154-40-34357-00

Instructions for use

Trulicity 0.75 mg

dulaglutide

Solution for injection in pre-filled pen



← Unfold and lay flat →



Read both sides for full instructions

ABOUT TRULICITY PRE-FILLED PEN

Please read these Instructions for use and the Patient 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 (0.75 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

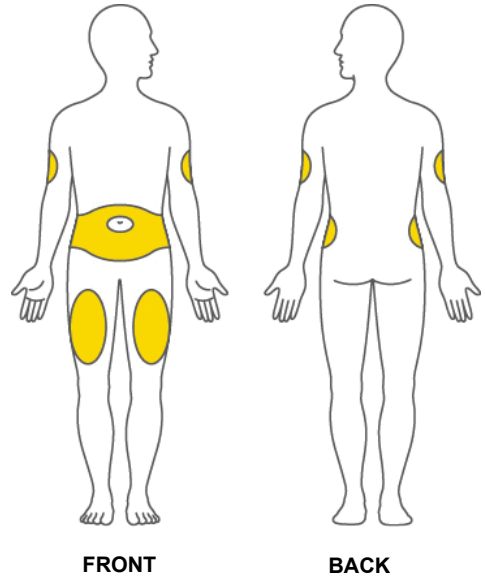
the pen. Do not use if you notice that the pen is damaged, or the medicine is cloudy, discolored or has particles in it.

Prepare

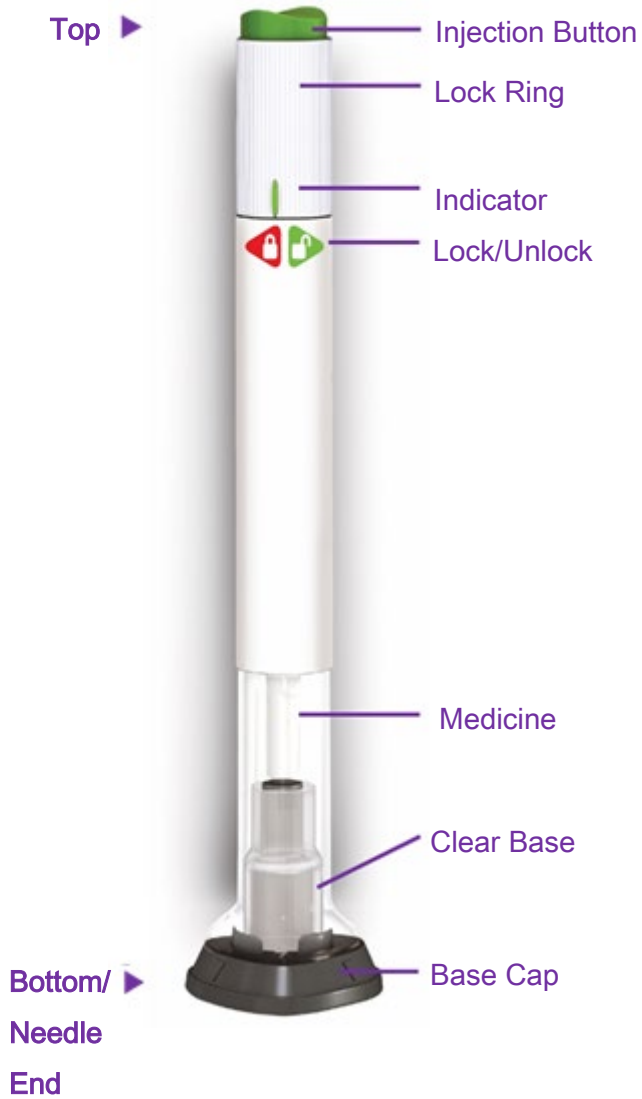
by washing your hands.

CHOOSE YOUR INJECTION SITE


- Your doctor 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**

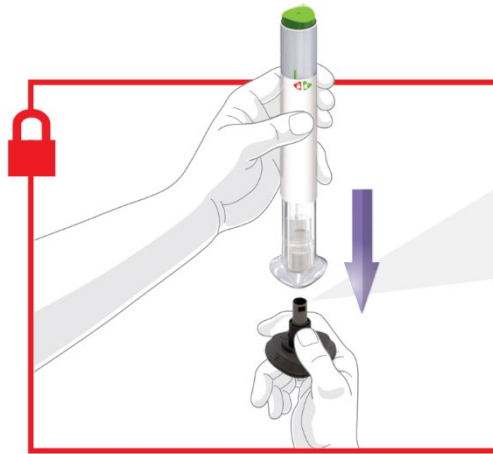


1 UNCAP

-  Make sure the pen is **locked**.
 - Pull off the gray base cap.

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

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



← **Gray base cap**

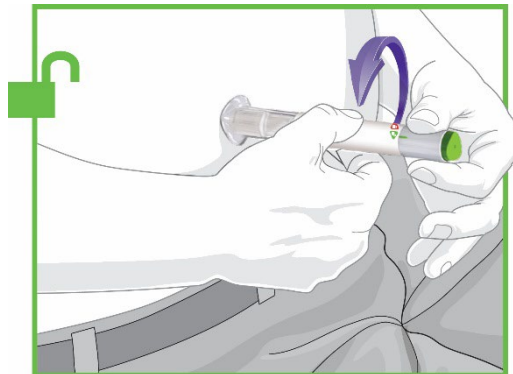
If the gray base cap does not look like the image above:

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

2 PLACE AND UNLOCK

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

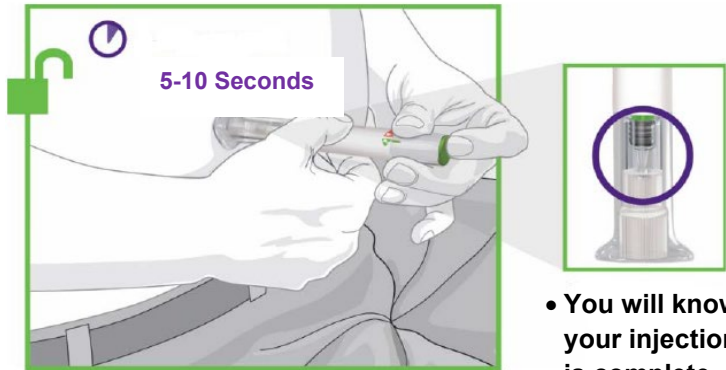
 **Unlock** by turning the lock ring.



3 PRESS AND HOLD

- 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.



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

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. If the pen has been left out of the refrigerator for more than 14 days, the pen must be discarded even if it has not reached the expiration date.
- 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 Patient Leaflet.

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 gray part is visible (see step 3). Also contact Eli Lilly Israel Ltd. (IL_PC_TE@lists.lilly.com) 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

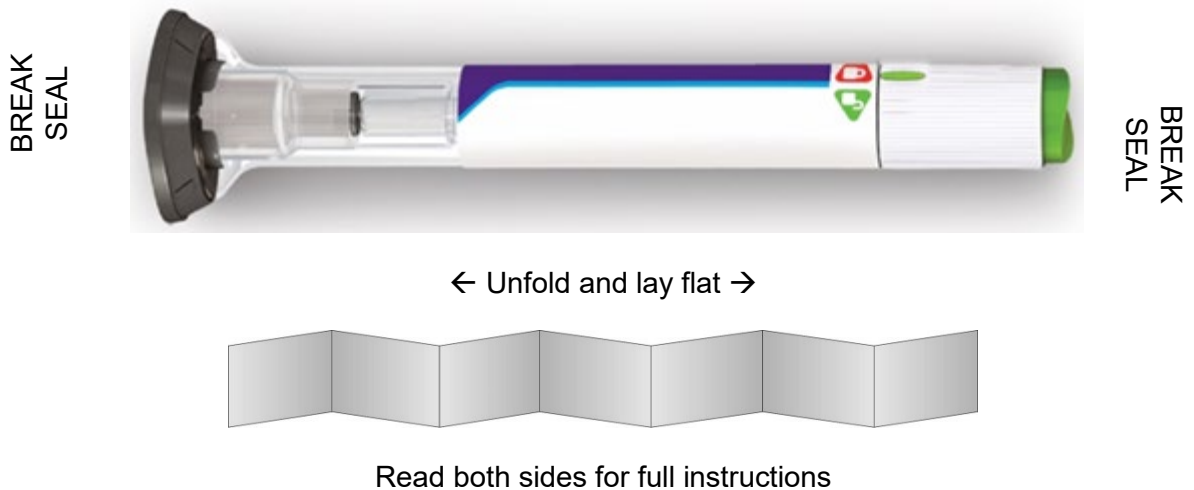
- If you have any questions or problems with your **Trulicity** pen, contact your doctor, pharmacist or nurse.

Instructions for use

Trulicity 1.5 mg

dulaglutide

Solution for injection in pre-filled pen



ABOUT TRULICITY PRE-FILLED PEN

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- The pen is a disposable, pre-filled delivery device that is ready to use. Each pen contains one weekly dose of Trulicity (1.5 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

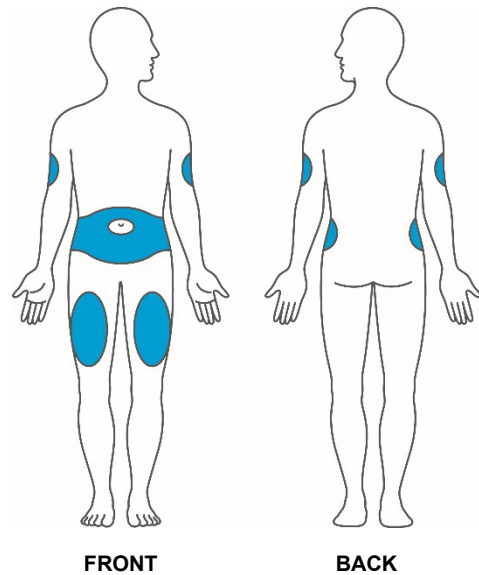
the pen. Do not use if you notice that the pen is damaged, or the medicine is cloudy, discolored or has particles in it.

Prepare

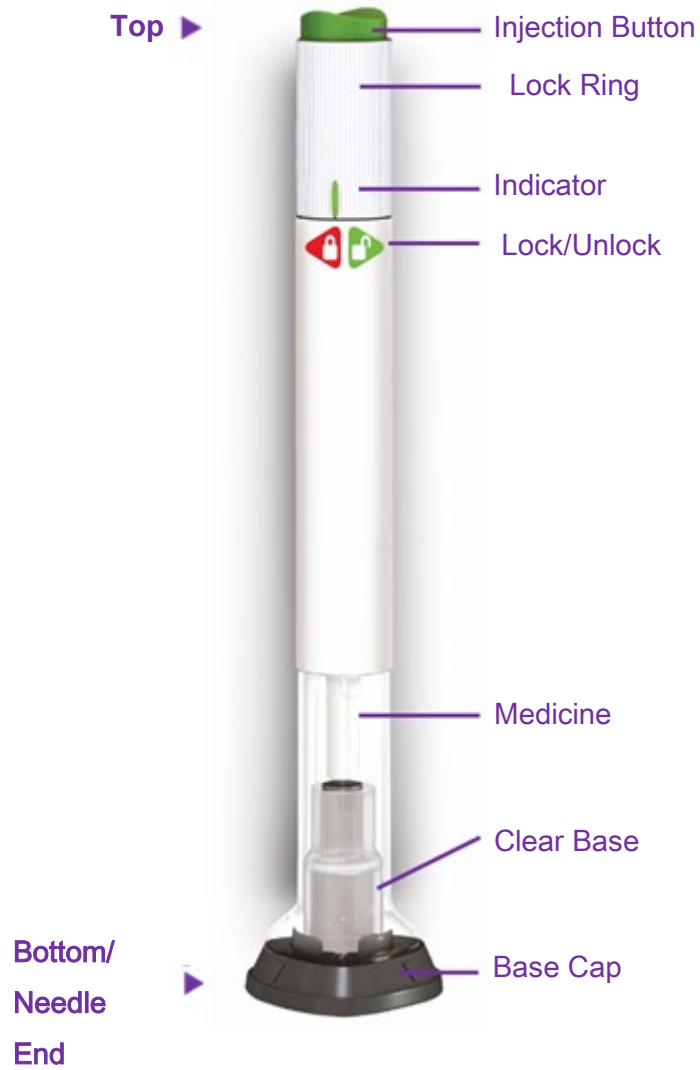
by washing your hands.

CHOOSE YOUR INJECTION SITE


- Your doctor 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**

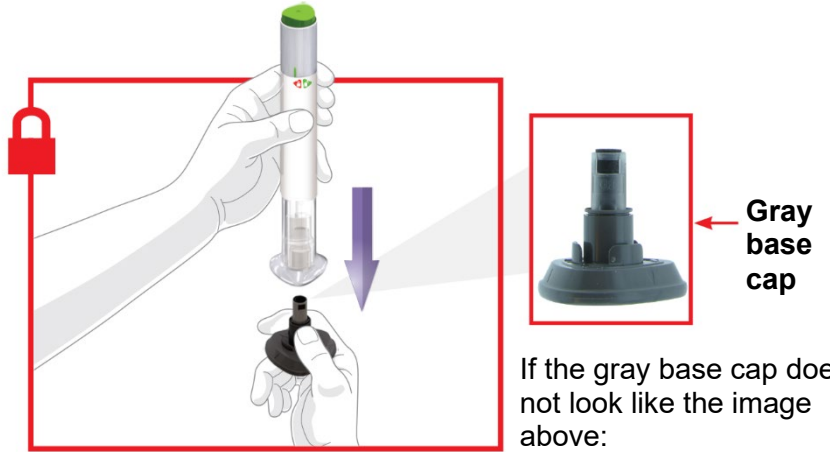


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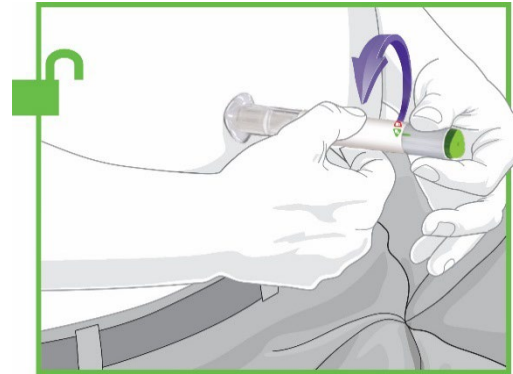
If the gray base cap does not look like the image above:

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

2 PLACE AND UNLOCK


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

 **Unlock** by turning the lock ring.

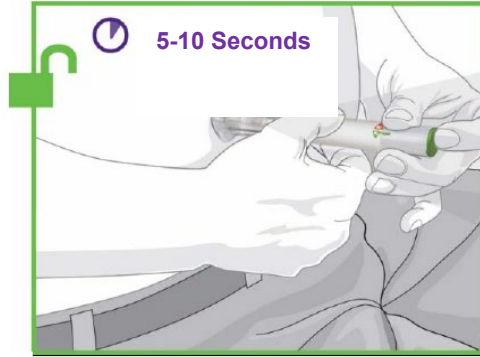


3 PRESS AND HOLD

- 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.



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

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.
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DISPOSAL OF PEN

- Dispose of the pen in a sharps container or as directed by your doctor, pharmacist or nurse.
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I'm not sure my pen worked correctly.

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WHERE TO LEARN MORE

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