

**PATIENT PACKAGE INSERT 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: See section 2 "Important information about some of the ingredients of this medicine" and section 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 their signs of illness are 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
- in addition to other medicinal products for the treatment of diabetes

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

Trulicity contains an active substance called dulaglutide and is used to lower blood sugar level (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 section 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.
 - you have type 1 diabetes (the type when your body does not produce any insulin). 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, nausea or vomiting, 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 slow emptying of the stomach (gastroparesis)].
 - you have ever had inflammation of the pancreas (pancreatitis) which causes severe pain in the stomach and back which does not go away.
 - you are taking a sulphonylurea or insulin to treat your diabetes, as low blood sugar level (hypoglycemia) can occur. Your doctor may need to change your dose of these other medicines to reduce this risk.
 - You suffer from kidney function problems.

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 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.

Interactions/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. Especially tell your doctor if you are taking:

- other medicines that lower the amount of sugar in your blood, such as: insulin or a medicine containing sulphonylurea. Your doctor may lower the dose of these other medicines to prevent you from getting low blood sugar levels (hypoglycemia). 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 hyperglycemia (high blood sugar levels) and diabetic ketoacidosis (a complication of diabetes that occurs when the body is unable to break down glucose because there is not enough insulin).

Use of this medicine and food

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

Pregnancy and Breastfeeding

It is not known if dulaglutide could harm the fetus. Women of child-bearing age should use contraception during treatment with dulaglutide. Tell your doctor if you are pregnant, think you

may be pregnant or are planning to get pregnant, as **Trulicity** should not be used during pregnancy. Talk to your doctor about the best way to control your blood sugar levels while you are pregnant.

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 levels (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 section 2, "Special warnings regarding the use of this medicine" 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.

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.

In certain situations, your doctor may recommend a starting dose of 0.75 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.

Trulicity can be used 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 product's box, 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.

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

Read the "Instructions for Use" for the pen carefully before using **Trulicity**.

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. An overdose of **Trulicity** may make your blood sugar levels too low (hypoglycemia) and can make you feel sick or be sick.

If you forget to take this medicine at the specified time and 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 remaining** 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.

If necessary, you can also change the day of the week on which you inject **Trulicity**, 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 consulting 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 people using this medicine. 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):

- Nausea (feeling sick) - this usually goes away over time
- Vomiting (being sick) - 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 treatment with dulaglutide but decrease over time in most patients.

- Hypoglycemia (low blood sugar level) is very common when dulaglutide is used with other medicines that contain metformin, 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):

- Hypoglycemia is common when dulaglutide is used alone or with both metformin and pioglitazone together. 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
- Gastroesophageal reflux disease (GERD) or heartburn - a disease caused by stomach acid coming up into the esophagus (the tube that connects your mouth to your stomach)
- 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

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, talk to 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.
Store refrigerated (2°C-8°C). Do not freeze.
Store in the original package 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 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 injections.

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 & Company Ltd., Indianapolis, Indiana, USA.

Revised in May 2021 according to MOHs guidelines.

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