

Medication Guide
TRULICITY® (TRU-li-si-tee)
(dulaglutide)
injection, for subcutaneous use

Read this Medication Guide before you start using TRULICITY and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or your treatment.

What is the most important information I should know about TRULICITY?

TRULICITY may cause serious side effects, including:

- **Possible thyroid tumors, including cancer.** Tell your healthcare provider if you get a lump or swelling in your neck, hoarseness, trouble swallowing, or shortness of breath. These may be symptoms of thyroid cancer. In studies with rats or mice, TRULICITY and medicines that work like TRULICITY caused thyroid tumors, including thyroid cancer. It is not known if TRULICITY will cause thyroid tumors or a type of thyroid cancer called medullary thyroid carcinoma (MTC) in people.
- Do not use TRULICITY if you or any of your family have ever had a type of thyroid cancer called medullary thyroid carcinoma (MTC), or if you have an endocrine system condition called Multiple Endocrine Neoplasia syndrome type 2 (MEN 2).

What is TRULICITY?

- TRULICITY is an injectable prescription medicine that is used:
 - along with diet and exercise to improve blood sugar (glucose) in adults and children 10 years of age and older with type 2 diabetes mellitus.
 - to reduce the risk of major cardiovascular events such as death, heart attack, or stroke in adults with type 2 diabetes mellitus with known heart disease or multiple cardiovascular risk factors.
- It is not known if TRULICITY can be used in people who have had pancreatitis.
- TRULICITY is not for use in people with type 1 diabetes.
- TRULICITY is not recommended for use in people with severe stomach or intestinal problems.
- It is not known if TRULICITY is safe and effective in children under 10 years of age.

Do not use TRULICITY if:

- you or any of your family have ever had a type of thyroid cancer called medullary thyroid carcinoma (MTC) or if you have an endocrine system condition called Multiple Endocrine Neoplasia syndrome type 2 (MEN 2).
- you have had a serious allergic reaction to dulaglutide or any of the ingredients in TRULICITY. See the end of this Medication Guide for a complete list of ingredients in TRULICITY. Symptoms of a serious allergic reaction include:
 - swelling of your face, lips, tongue or throat
 - problems breathing or swallowing
 - severe rash or itching
 - fainting or feeling dizzy
 - very rapid heartbeat

Before using TRULICITY, tell your healthcare provider about all of your medical conditions, including if you:

- have or have had problems with your pancreas, kidneys or liver.
- have severe problems with your stomach, such as slowed emptying of your stomach (gastroparesis) or problems with digesting food.
- have a history of diabetic retinopathy.
- are pregnant or plan to become pregnant. It is not known if TRULICITY will harm your unborn baby. Tell your healthcare provider if you become pregnant while using TRULICITY.
- are breastfeeding or plan to breastfeed. It is not known if TRULICITY passes into your breast milk. You and your healthcare provider should decide if you should breastfeed while taking TRULICITY.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. TRULICITY may affect the way some medicines work, and some medicines may affect the way TRULICITY works.

Before using TRULICITY, tell your healthcare provider if you are taking other medicines to treat diabetes including insulin or sulfonylureas which could increase your risk of low blood sugar. Talk to your healthcare provider about low blood sugar and how to manage it.

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I use TRULICITY?

- Read the **Instructions for Use** that comes with TRULICITY.
- Use TRULICITY exactly as your healthcare provider tells you to.
- TRULICITY is injected under the skin (subcutaneously) of your stomach (abdomen), thigh, or upper arm.
- **Use TRULICITY 1 time each week on the same day each week at any time of the day.**
- You may change the day of the week as long as your last dose was given **3** or more days before.
- If you miss a dose of TRULICITY, take the missed dose as soon as possible if there are at least **3** days (72 hours) until your next scheduled dose. If there are less than **3** days remaining, skip the missed dose and take your next dose on the regularly scheduled day. **Do not** take **2** doses of TRULICITY within **3** days of each other.
- TRULICITY may be taken with or without food.
- **Do not** mix insulin and TRULICITY together in the same injection.
- You may give an injection of TRULICITY and insulin in the same body area (such as, your stomach area), but not right next to each other.
- Change (rotate) your injection site with each weekly injection. **Do not** use the same site for each injection.
- If you take too much TRULICITY, call your healthcare provider or go to the nearest emergency room right away.

What are the possible side effects of TRULICITY?

TRULICITY may cause serious side effects, including:

- See “**What is the most important information I should know about TRULICITY?**”
- **Inflammation of your pancreas (pancreatitis).** Stop using TRULICITY and call your healthcare provider right away if you have severe pain in your stomach area (abdomen) that will not go away, with or without vomiting. You may feel the pain from your abdomen to your back.
- **Low blood sugar (hypoglycemia).** Your risk for getting low blood sugar may be higher if you use TRULICITY with another medicine that can cause low blood sugar, such as a sulfonylurea or insulin.

Signs and symptoms of low blood sugar may include:

- dizziness or light-headedness
 - blurred vision
 - anxiety, irritability, or mood changes
 - sweating
 - slurred speech
 - hunger
 - confusion or drowsiness
 - shakiness
 - weakness
 - headache
 - fast heartbeat
 - feeling jittery
- **Serious allergic reactions.** Stop using TRULICITY and get medical help right away if you have any symptoms of a serious allergic reaction including:
 - swelling of your face, lips, tongue or throat
 - fainting or feeling dizzy
 - problems breathing or swallowing
 - very rapid heartbeat
 - severe rash or itching
 - **Kidney problems (kidney failure).** In people who have kidney problems, diarrhea, nausea, and vomiting may cause a loss of fluids (dehydration) which may cause kidney problems to get worse.
 - **Severe stomach problems.** Other medicines like TRULICITY may cause severe stomach problems. It is not known if TRULICITY causes or worsens stomach problems.
 - **Changes in vision.** Tell your healthcare provider if you have changes in vision during treatment with TRULICITY.
 - **Gallbladder problems.** Gallbladder problems have happened in some people who take TRULICITY. Tell your healthcare provider right away if you get symptoms of gallbladder problems, which may include:
 - pain in your upper stomach (abdomen)
 - yellowing of skin or eyes (jaundice)
 - fever
 - clay-colored stools

The most common side effects of TRULICITY may include:

- nausea
- stomach (abdominal) pain
- diarrhea
- decreased appetite
- vomiting

Tell your healthcare provider if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of TRULICITY. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about the safe and effective use of TRULICITY.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use TRULICITY for a condition for which it was not prescribed. Do not give TRULICITY to other people, even if they have the same symptoms you have. It may harm them.

This Medication Guide summarizes the most important information about TRULICITY. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about TRULICITY that is written for health professionals.

What are the ingredients in TRULICITY?

Active ingredient: dulaglutide

Inactive ingredients: citric acid anhydrous, mannitol, polysorbate 80, trisodium citrate dihydrate, in water for injection
TRULICITY® is a registered trademark of Eli Lilly and Company.

Manufactured by: Eli Lilly and Company, Indianapolis, IN 46285, USA, US License Number 1891
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For more information, go to www.TRULICITY.com or call 1-800-545-5979.

This Medication Guide has been approved by the U.S. Food and Drug Administration

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