PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

TRULICITY®

1,5 mg/0,5 mL solution for injection

Dulaglutide

Read all of this leaflet carefully before you start using TRULICITY

- Keep this leaflet. You may need to read it again
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.

TRULICITY has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

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 is used to lower blood sugar (glucose) and reduce the risk of major cardiovascular events in adults with type 2 diabetes mellitus.

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 when your blood sugar is not properly controlled by diet and exercise alone either on its own or with other medicines for diabetes, when other medicines are not enough to control your blood sugar levels.

TRULICITY is used 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 important to continue to follow the advice on diet and exercise given to you by your doctor or other healthcare professional.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE TRULICITY

Do not take TRULICITY:

- If you are hypersensitive (allergic) to dulaglutide or any of the other ingredients of TRULICITY (listed in section 6).
- 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).
- If you have ever had pancreatitis (inflammation of the pancreas) which causes severe pain in the stomach and back which does not go away.
- If you have type 1 diabetes (the type when your body does not produce any insulin) as TRULICITY may not be right for you.
- If 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.

- If you have severe problems with food digestion or food remaining in your stomach for longer than normal (including gastroparesis).

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using TRULICITY if:

- you are on dialysis as TRULICITY is not recommended.
- you have type 1 diabetes (the type when your body does not produce any insulin) as TRULICITY 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 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 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 other medicines 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.

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 is not recommended for children and adolescents under 18 years of age because it has not been studied in these patients.

Other medicines and TRULICITY

Tell your doctor, pharmacist or nurse if you are using, have recently used or might use any other medicine.

Especially tell your doctor:

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

Pregnancy, breastfeeding and fertility

It is not known if TRULICITY could harm your unborn child. Women who could become pregnant should use contraception during treatment with TRULICITY. 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.

Talk to your doctor if you would like to or are breastfeeding before taking TRULICITY. Do not use TRULICITY if you are breastfeeding. It is not known if dulaglutide passes into human breast milk.

The effect of TRULICITY on fertility in humans is unknown. In animal studies, there was no direct effect on mating or fertility following treatment with TRULICITY.

Driving and using machines

If you use TRULICITY in combination with a sulphonylurea or insulin, low blood sugar (hypoglycaemia) may occur which may reduce your ability to concentrate. Please keep this in mind in all situations where you might put yourself and others at risk (e.g. driving a car or using machines).

3. HOW TO USE TRULICITY

Always use TRULICITY exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure how to use it.

The recommended dose is 1,5 mg once a week. Each pen contains one weekly dose of TRULICITY (1,5 mg). Each pen delivers only one dose.

You can use your TRULICITY 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 TRULICITY 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 TRULICITY may make your blood sugar too low (hypoglycaemia) and can make you feel sick or be sick.

If you forget to take 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 then 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

TRULICITY 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

- Nausea (feeling sick)
- Vomiting (being sick)
- Diarrhoea
- Abdominal (stomach) pain.

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

- Hypoglycaemia (low blood sugar) is very common when TRULICITY is used with medicines that contain metformin, a sulphonylurea and/or insulin.

Common: may affect up to 1 in 10 people

- Hypoglycaemia is common when TRULICITY is used alone, or with both metformin and pioglitazone together, or with a sodium-glucose co-transporter 2 inhibitor (SGLT2i) with or without metformin.
- 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.
- Feeling less hungry (decreased appetite)
- Indigestion
- Constipation
- Gas (flatulence)
- Bloating of the stomach
- Gastroesophageal reflux disease - 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 1 in 1 000 people
- A delay in the emptying of the stomach.

Reporting of side effects

If you get side effects, talk to your doctor or, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of TRULICITY.

Alternately, report suspected adverse events to the company at: ade_za@lilly.com

5. HOW TO STORE TRULICITY

Store all medicines out of the sight and reach of children.

Do not use TRULICITY 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 ºC.

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

Do not throw away/dispose of any medicines via drains or sewerage systems (e.g. toilets). Return unused medicine to your pharmacist or ask your pharmacist how to dispose of 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. Each pre-filled pen contains 1,5 mg of dulaglutide in 0,5 mL solution. The other ingredients are trisodium citrate dihydrate; citric acid anhydrous; mannitol; polysorbate 80 and water for injections.

What TRULICITY looks like and contents of the pack

TRULICITY is a clear, colourless, sterile 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.

Available in packs of 2 and 4. Not all pack sizes may be marketed.

Holder of the Certificate of Registration

Eli Lilly (S.A.) (Pty) Limited

Private Bag X119, 2021

Golden Oak House (Building E), Ballyoaks Office Park,

35 Ballyclare Drive

Bryanston, 2191

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