

Ireland and Northern Ireland Only



A practical guide for Healthcare Professionals

Prescribing Information and adverse event reporting
can be found on the inside back cover



trulicity®
dulaglutide once-weekly injection



Lilly

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This booklet covers some key information for when you decide to prescribe Trulicity for adults with type 2 diabetes.

The information in this booklet is supplemented by the Prescribing Information, which can be found on the inside back cover.



1.5mg pen shown for illustrative purposes only. Other doses are available.



Indication and dosing¹

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.

- The recommended dose is 0.75 mg once weekly

As **add-on therapy** when in addition to other medicinal products for the treatment of diabetes.

- The recommended dose is 1.5 mg once weekly
- For potentially vulnerable populations 0.75 mg once weekly can be considered as a starting dose

For **additional glycaemic control**,

- the 1.5 mg dose may be increased after at least 4 weeks to 3 mg once weekly.
- the 3 mg dose may be increased after at least 4 weeks to 4.5 mg once weekly.

The maximum dose is 4.5 mg once weekly



Trulicity licence¹

Specific patient populations

Patients with renal impairment

- No dose adjustment is required in patients with mild, moderate or severe renal impairment (eGFR <90 to ≥ 15 mL/min/1.73m²)
- There is very limited experience in patients with end stage renal disease (<15 mL/min/1.73 m²), therefore Trulicity can not be recommended in this population

Patients with hepatic impairment

- No dose adjustment is required in patients with hepatic impairment

Elderly patients

- No dose adjustment is required based on age.

Special warnings and precautions for use

Dulaglutide should not be used in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis.

Addition to sulphonylurea (SU) and/or insulin

When it is added to existing therapy of a sulphonylurea or insulin, a reduction in the dose of sulphonylurea or insulin may be considered to reduce the risk of hypoglycaemia. Blood glucose self-monitoring is necessary to adjust the dose of SU/ insulin, particularly when Trulicity therapy is started and insulin is reduced. Diabetic ketoacidosis has been reported in insulin-dependent patients after rapid discontinuation or dose reduction of insulin. A stepwise approach to insulin dose reduction is recommended.

Dehydration

Dehydration, sometimes leading to acute renal failure or worsening renal impairment, has been reported in patients treated with dulaglutide. Many of the reported adverse renal



Trulicity licence¹ (cont.)

events occurred in patients who had experienced nausea, vomiting, diarrhoea, or dehydration. Patients treated with dulaglutide should be advised of the potential risk of dehydration, particularly in relation to gastrointestinal adverse reactions and take precautions to avoid fluid depletion.

Dulaglutide has not been studied in patients with severe gastrointestinal disease, including severe gastroparesis, and is therefore not recommended in these patients.

Acute pancreatitis

Use of GLP-1 receptor agonists has been associated with a risk of developing acute pancreatitis. In clinical trials and the post-marketing setting, acute pancreatitis has been reported in association with dulaglutide. Patients should be informed of the characteristic symptoms of acute pancreatitis. If pancreatitis is suspected, dulaglutide should be discontinued. If pancreatitis is confirmed, dulaglutide should not be restarted. In the absence of other signs and symptoms of acute pancreatitis, elevations in pancreatic enzymes alone are not predictive of acute pancreatitis.

Indicated as an add-on therapy in combination with other medicinal products for the treatment of diabetes

Metformin and/or pioglitazone

- When Trulicity is added to existing metformin and/or pioglitazone therapy, the current dose of metformin and/or pioglitazone can be continued.

SGLT2i

- When Trulicity is added to existing metformin and/or sodium-glucose co-transporter 2 inhibitor (SGLT2i) therapy, the current dose of metformin and/or SGLT2i can be continued.

Sulphonylurea (SU) and/or insulin

Please see Special warnings and precautions for use on page 6



Ready-to-use pen²

Designed with the patient in mind

The Trulicity pen is ready to use

- No reconstitution or priming required
- Preattached, 29-gauge hidden needle
- Each pen contains a single fixed dose of Trulicity
- The needle insertion depth (when injecting) is approximately 5mm

Automatic dose delivery

- Automatically delivers a dose at the press of a button
- Injection process takes 5-10 seconds
- Needle automatically retracts following injection

In a 4-week usability study with injection-naïve patients (n=210), 99% found the ready-to-use pen easy to use²

The Trulicity pen

Trulicity is available in four doses: 0.75mg, 1.5mg, 3mg, 4.5mg

(please see licensed indications on page 5)



Trulicity's
ready-to-use pen

EAN numbers and PIP codes:

Trulicity 0.75 mg

EAN Code: 5014602101565

Pip Code: 394-0475

Trulicity 1.5 mg

EAN Code: 5014602101572

Pip Code: 394-0483

Trulicity 3 mg

EAN Code: 5014602101787

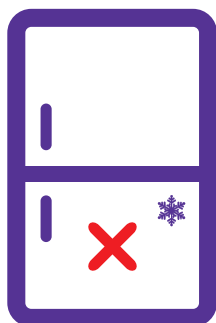
Pip Code: 416-3705

Trulicity 4.5 mg

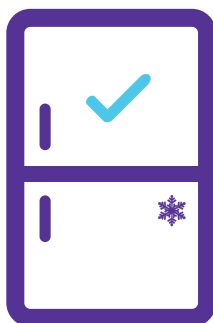
EAN Code: 5014602101794

Pip Code: 416-3713

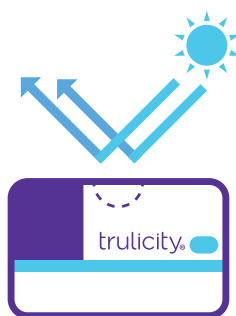
Storage



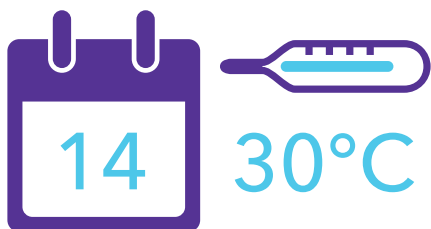
Do not freeze



Store in a
refrigerator
(2°C to 8°C)



Store in original
packaging in
order to protect
from light



In use - Trulicity may be stored unrefrigerated at a temperature not above 30°C for up to 14 days



Refrigerated shelf life



Dosing frequency¹

- Trulicity offers once-weekly administration
- Trulicity can be taken at any time of day, independent of meals

What should a patient do if they miss their dose?

- t A missed dose can be taken if there are at least 3 days until the next scheduled dose
- t The next dose should then be taken on the next normal dosing day
- ✗ Do not advise patients to take 2 doses of Trulicity within 72 hours of each other

Example: Normal dose day is Monday

Mon	Tue	Wed	Thu	Fri	Sat	Sun	Mon
t			→	✗	✗	✗	t

- ✗ Trulicity should not be taken on these days. A patient should not take 2 doses of Trulicity within 72 hours of each other
- t The next dose should be taken on the next normal dosing day

Disposal

Used Trulicity pens contain a recessed needle and should be disposed of in a sharps bin.

These are examples of two medicinal sharps bins available on the NHS Electronic Drug Tariff and Scottish Drug Tariff:^{3,4}

- Sharpsafe (1 litre)
- Sharpsguard Yellow (1 litre)

Closed Sharpsafe container

(1 litre) - up to 7 Trulicity pens*



H 18cm W 8.1cm D 7.5cm

Closed Sharpsguard container

(1 litre) - up to 5 Trulicity pens*



H 11.4cm W 20.4cm D 6.8cm

Please ensure your patients are aware of the local procedures for safe disposal of their Trulicity pen and sharps bins.

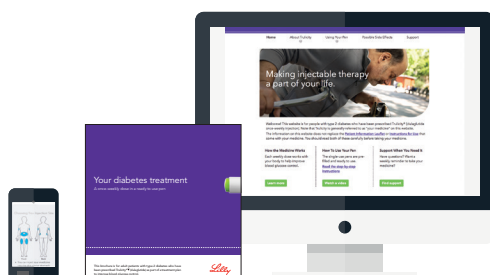
*These sharps containers were both tested with demonstration Trulicity pens. These quantities are achievable if the sharps containers are empty and if the pens are inserted without the grey base cap.



Resources available to help you and your patients

- Trulicity HCP and Patient Websites
lillydiabetes.co.uk (UK only)
- Patient Brochure*
 - [Contact card](#) – states the medicine the patient is taking and allows them to keep your contact details to hand
 - [Weekly reminder stickers](#) – to mark the dosing day on their calendar at home
- Trulicity Reminder App (UK only)
 - [Weekly reminder function](#)
 - [Patient demonstration video](#)

*Contact your Lilly Representative for more information



TRULICITY® (dulaglutide) PRESCRIBING INFORMATION

Ireland and United Kingdom (Northern Ireland)

Presentation Dulaglutide solution for injection in a pre-filled pen. Each single-use pen contains either 0.75 mg, 1.5 mg, 3 mg or 4.5 mg of dulaglutide in 0.5 ml solution. **Uses** Dulaglutide 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 inappropriate due to intolerance or contraindications, or in addition to other medicinal products for the treatment of diabetes. **Dosage and Administration** *Monotherapy:* Recommended dose 0.75 mg once weekly. *Add-on therapy:* Recommended dose 1.5 mg once weekly. For potentially vulnerable patients, 0.75 mg once weekly can be considered as a starting dose. *Additional glycaemic control:* The 1.5 mg dose may be increased after at least 4 weeks to 3 mg once weekly. The 3 mg dose may be increased after at least 4 weeks to 4.5 mg once weekly. The maximum dose is 4.5 mg once weekly. Trulicity is administered as a subcutaneous injection in the abdomen, thigh, or upper arm. It should not be administered intravenously or intramuscularly. The dose can be administered at any time of day, with or without meals. When Trulicity is added to existing metformin and/or pioglitazone therapy, the current dose of metformin and/or pioglitazone can be continued. When Trulicity is added to existing metformin and/or sodium-glucose co-transporter 2 inhibitor (SGLT2) therapy, the current dose of metformin and/or SGLT2 can be continued. When it is added to existing sulphonylurea or insulin therapy, a reduction in the dose of sulphonylurea or insulin may be considered to reduce the risk of hypoglycaemia. Blood glucose self-monitoring is necessary to adjust the dose of sulphonylurea or insulin, particularly when Trulicity therapy is started and insulin is reduced. A stepwise approach to insulin dose reduction is recommended. *Elderly:* No dose adjustment is required based on age. *Renal impairment:* No dose adjustment is required in mild, moderate or severe renal impairment (eGFR < 90 to ≥ 15 mL/min/1.73 m²). Not recommended in end stage renal disease (< 15 mL/min/1.73 m²). *Hepatic impairment:* No dose adjustment is required. *Paediatric:* The safety and efficacy of dulaglutide in children < 18 years have not been established. No data are available. **Contra-indications** Hypersensitivity to the active substance or to any of the excipients. **Warnings and Special Precautions** *Traceability:* In order to improve the traceability of biological medicinal products, the name and the batch number of the administered medicinal product should be clearly recorded. Dulaglutide should not be used in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis. Dulaglutide is not a substitute for insulin. Diabetic ketoacidosis has been reported in insulin-dependent patients after rapid discontinuation or dose reduction of insulin. Not recommended in patients with severe gastrointestinal disease, including severe gastroparesis. Dehydration, sometimes leading to acute renal failure or worsening renal impairment, has been reported in patients treated with dulaglutide, especially at the initiation of treatment. Many of the reported adverse renal events occurred in patients who had experienced nausea, vomiting, diarrhoea, or dehydration. Patients treated with dulaglutide should be advised of the potential risk of dehydration, particularly in relation to gastrointestinal adverse reactions and take precautions to avoid fluid depletion. In clinical trials and the post-marketing setting, acute pancreatitis has been reported in association with dulaglutide. Patients should be informed of the characteristic symptoms of acute pancreatitis. If pancreatitis is suspected, dulaglutide should be discontinued. If pancreatitis is confirmed, dulaglutide should not be restarted. Use of dulaglutide in combination with a sulphonylurea or insulin may increase the risk of hypoglycaemia. The risk of hypoglycaemia may be lowered by a reduction in the dose of sulphonylurea or insulin. Trulicity is essentially sodium-free (< 1 mmol sodium (23 mg) per dose). **Interactions** Dulaglutide delays gastric emptying. For patients receiving dulaglutide in combination with oral medicinal products with rapid gastrointestinal absorption or prolonged release, there is a potential for altered medicinal product exposure, particularly at the time of dulaglutide treatment initiation. In the clinical pharmacology studies, dulaglutide doses up to 1.5 mg

did not affect the absorption of the orally administered medicinal products tested to any clinically relevant degree. No dose adjustments of paracetamol, atorvastatin, digoxin, lisinopril, metoprolol, warfarin, oral contraceptives, or metformin (immediate release formula) are required when given together with dulaglutide 1.5 mg. For the 4.5 mg dose, absence of major clinically relevant interactions was predicted by physiologically-based pharmacokinetic (PBPK) modelling simulations. For further details of these interaction studies, please see the Summary of Product Characteristics. **Fertility, pregnancy and lactation** Not recommended during pregnancy. Should not be used if breast-feeding. Effect on fertility is unknown. **Effects on ability to drive and use machines** When used in combination with a sulphonylurea or insulin, patients should be advised to take precautions to avoid hypoglycaemia while driving and using machines. **Undesirable Effects** *Very common* (≥ 1/10): Hypoglycaemia (when used in combination with insulin, glimepiride, metformin, or metformin plus glimepiride), nausea, diarrhoea, vomiting, abdominal pain. *Common* (≥ 1/100 to < 1/10): Hypoglycaemia (when used as monotherapy, in combination with metformin plus pioglitazone, or in combination with an SGLT2 inhibitor with or without metformin), decreased appetite, dyspepsia, constipation, flatulence, abdominal distention, gastro-oesophageal reflux disease, eructation, fatigue, sinus tachycardia, first-degree atrioventricular block (AVB). *Uncommon* (≥ 1/1,000 to < 1/100): Hypersensitivity, dehydration, injection site reactions, cholelithiasis, cholecystitis. *Rare* (≥ 1/10,000 to < 1/1,000): Acute pancreatitis, anaphylactic reaction, angioedema. *Not Known* (cannot be estimated from available data): Non-mechanical intestinal obstruction. None of the patients with systemic hypersensitivity developed dulaglutide anti-drug antibodies. The safety profile in patients treated with dulaglutide 3 mg and 4.5 mg once weekly is consistent with that described for dulaglutide doses of 0.75 mg and 1.5 mg once weekly. For full details of these and other side-effects, please see the Summary of Product Characteristics, which is available at **UK (Northern Ireland):** <https://www.emcmedicines.com/en-gb/northernireland/>, or **Ireland:** <http://www.medicines.ie/> **Legal Category** POM **Marketing Authorisation Numbers and Holder** EU/1/14/956/002 EU/1/14/956/007 EU/1/14/956/012 EU/1/14/956/015. Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, The Netherlands **Cost (UK only)** £73.25 per pack of 4 single use pens (0.75 mg) £73.25 per pack of 4 single use pens (1.5 mg) £73.25 per pack of 4 single use pens (3 mg) £73.25 per pack of 4 single use pens (4.5 mg) *An Irish price is available on request; please see section below for contact information.* **Date of Preparation or Last Review** October 2021 **Further Information is Available From** Eli Lilly and Company Limited, Lilly House, Basing View, Basingstoke, Hampshire, RG21 4FA. Telephone: **UK (Northern Ireland):** + 44-(0) 1256 315000, **Ireland:** + 353-(0) 1 661 4377 E-mail: ukmedinfo@lilly.com

Adverse events and product complaints should be reported.

Reporting forms and information can be found at UK (Northern Ireland): www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store, or Ireland: www.hpra.ie.

Adverse events and product complaints should also be reported to Lilly: please call Lilly on 01256 315 000 (UK), or 01 664 0446 (IE).

REFERENCES

1. Trulicity Summary of Product Characteristics. 2. Matfin G et al. J Diabetes Sci Technol. 2015; 9(5): 1071-1079.
3. NHS Electronic Drug Tariff: Part IXA - Appliances - Accessories. Available from: <http://www.drugtariff.nhsbsa.nhs.uk/#/00451251-DA/DA00451088/Part IXA-Appliances> [Accessed November 2020]
4. Scottish Drug Tariff: Appliances. Needle Clicking (Chopping) Device. 2019. Available from <https://www.isdscotland.org/Health-Topics/Prescribing-and-Medicines/Scottish-Drug-Tariff/Docs/Feb-2019/2019-02-SDT-PART3.pdf> [Accessed November 2020]



To learn more about how Trulicity could help your patients with type 2 diabetes

- Visit lillydiabetes.co.uk (UK only)
- Contact your Lilly Representative
- Call your local Lilly office:
UK +44 (0) 1256 315000
IE +353 (0) 1661 4377



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