



DATE

Trulicity® (dulaglutide) 1.5 mg solution for injection in pre-filled pen, Batch Specific Variation, Batch D761603A, D764386A.

Dear Healthcare Professional,

Lilly House,
Basing View
Basingstoke
Hampshire
RG21 4FA

Eli Lilly and Company (Lilly) in agreement with the Medicines and Healthcare products Regulatory Agency (MHRA) wish to inform you of the following:

Summary:

To help improve supply for dulaglutide patients, approval has been granted for a batch specific variation to allow the company to use US packs. There is no product quality, safety or efficacy impact related to the use of these US Trulicity batches.

Product	US Batch Number	Expiration Date
Trulicity® 1.5 mg solution for injection in pre-filled pen	D761603A	2026-APR-09
Trulicity® 1.5 mg solution for injection in pre-filled pen	D764386A	2026-APR-19

Background information:

Indication

Trulicity is indicated for the treatment of patients 10 years and above 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.

Advice for healthcare professionals

- Healthcare professionals (HCPs) (especially prescribers) are advised to ask patients to read the UK patient information leaflet (PIL) that the pharmacist will give them before taking the medicine and also share electronic links to the PIL with patients (these links are also listed in the patient letter that will be given to patients with the medicine).
- HCPs should discard the US PIL that comes in these medicines' packs.
- Lilly will provide pharmacists with the UK PIL and patient letter with the medicines. HCPs (especially dispensers) should ensure that patients are given the patient letter and the hardcopy of the UK PIL when patients are given these medicines.
- Links to UK PIL and Summary of Product Characteristics (SmPC) can be found here:
 - [TRULICITY 1.5 mg solution for injection in pre-filled pen - Patient Information Leaflet \(PIL\) - \(emc\)](#)

- [TRULICITY 1.5 mg solution for injection in pre-filled pen - Summary of Product Characteristics \(SmPC\) - \(emc\)](#)

Call for reporting:

Please continue to report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card scheme.

Please report:

- all suspected ADRs that are serious or result in harm. Serious reactions are those that are fatal, life-threatening, disabling or incapacitating, those that cause a congenital abnormality or result in hospitalisation, and those that are considered medically significant for any other reason

You can report via:

- the [Yellow Card website](#)
- the free Yellow Card app available from the [Apple App Store](#) or [Google Play Store](#)
- some clinical IT systems (EMIS/SysmOne/Vision/MiDatabank) for healthcare professionals

Alternatively, you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm. You can leave a message outside of these hours.

When reporting, please provide as much information as possible, including information about medical history, any concomitant medication, timing onset, treatment dates, and product brand name.

We remind you of the importance of reporting any suspected adverse reactions, including medication errors or product complaints, related to Trulicity to your local competent authority (MHRA).

Additionally, you can report adverse events or product complaints among patients taking Trulicity to Lilly. Please contact Lilly Medical Information department at: 01256 315000 or via email: ukmedinfo@lilly.com.

This letter is not intended as a complete description of the benefits and risks related to the use of Trulicity, please see the SmPC for full details.

Company contact point:

Please contact the Lilly Medical Information department using the above details if you have any questions about the information in this letter or the safe and effective use of Trulicity.

Sincerely,

Appropriate Lilly Signee,
Title, Department

