08-Apr-2024

IMPORTANT COMMUNICATION

Subject: Extended Use Beyond Printed Expiry Date for Mounjaro® 2.5 mg KwikPen® solution for injection in pre-filled pen, Batch D712074.

Dear Patient,

Eli Lilly and Company (Lilly) wish to inform you of an important information update about Mounjaro® 2.5 mg KwikPen® solution for injection in pre-filled pen:

The product has been validated with new stability data to support an extension of shelf life from 9 months to 14 months, which the MHRA approved on 25-Mar-2024.

Your Mounjaro® 2.5mg KwikPen® which has a printed expiration date of 05-2024 on the carton and pen can now be used until 10-2024.

Product	Batch Number	Displayed/Printed Expiry Date (MM-YYYY)	New Expiry Date (MM-YYYY)
Mounjaro® 2.5mg KwikPen® solution for injection in pre-filled pen	D712074	05-2024	10-2024

The product of these specific batches will continue to work safely and as intended within the allowed extended use by date.

Your healthcare professional has already been notified about this update. If you have any further questions on the use of this medicine, ask your prescribing healthcare professional, your dispensing pharmacist, or contact Lilly Medical Information department at: 01256 315000 or via email: ukmedinfo@lilly.com.

Sincerely,

Joanne Webb

Joanne Webb
Senior Medical Director
Eli Lilly and Company

08-Apr-2024

IMPORTANT COMMUNICATION

Subject: Extended Use Beyond Printed Expiry Date for Mounjaro® 2.5 mg KwikPen® solution for injection in pre-filled pen, Batches D720751, D720957

Dear Patient,

Eli Lilly and Company (Lilly) wish to inform you of an important information update about Mounjaro® 2.5 mg KwikPen® solution for injection in pre-filled pen:

The product has been validated with new stability data to support an extension of shelf life from 9 months to 14 months, which the MHRA approved on 25-Mar-2024.

Your Mounjaro® 2.5mg KwikPen® which has a printed expiration date of 09-2024 on the carton and pen can now be used until 02-2025.

Product	Batch Number	Displayed/Printed Expiry Date (MM-YYYY)	New Expiry Date (MM-YYYY)
Mounjaro® 2.5mg KwikPen® solution for injection in pre-filled pen	D720751 D720957	09-2024	02-2025

The product of these specific batches will continue to work safely and as intended within the allowed extended use by date.

Your healthcare professional has already been notified about this update. If you have any further questions on the use of this medicine, ask your prescribing healthcare professional, your dispensing pharmacist, or contact Lilly Medical Information department at: 01256 315000 or via email: ukmedinfo@lilly.com.

Sincerely,

Joanne Webb

Joanne Webb
Senior Medical Director
Eli Lilly and Company

08-Apr-2024

Direct Healthcare Professional Communication (DHPC)

Subject: Mounjaro® ▼(tirzepatide) 2.5 mg KwikPen® solution for injection in pre-filled pen: Extended Use Beyond Printed Expiry Date, Batches D712074, D720751, D720957

Dear Healthcare Professional:

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

Summary

- **There has been an extension to the shelf life of all units of Mounjaro® 2.5mg KwikPen® belonging to batch D712074, D720751, and D720957, they now have a longer shelf life of 14 months.**
- **Patients can continue to use Mounjaro® 2.5 Kwikpen® of these specified batches until the extended expiry date, as listed in the background information Section Table 1.**

Background information

Mounjaro is indicated:

1. 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
   - in addition to other medicinal products for the treatment of diabetes.

2. For weight management, including weight loss and weight maintenance, as an adjunct to a reduced-calorie diet and increased physical activity in adults with an initial Body Mass Index (BMI) of

   - ≥ 30 kg/ m^2 (obesity) or
   - ≥ 27 kg/m^2 to < 30 kg/m^2 (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, dyslipidaemia, obstructive sleep apnoea, cardiovascular disease, prediabetes, or type 2 diabetes mellitus).

Mounjaro was validated with new stability data to support an extension of shelf life from 9 months to 14 months, which the MHRA has approved on 25-Mar-2024.

The affected Mounjaro packs, within these batches, will not be re-labelled, but will be inserted into a sealed clear plastic bag with a letter advising the patients to follow the below indicated New Expiry Date.

Table 1: Affected batches for extended use of Mounjaro® 2.5 mg KwikPen®

Product	Batch Number	Displayed/Printed Expiry Date (MM-YYYY)	New Expiry Date (MM-YYYY)
Mounjaro® 2.5mg KwikPen® solution for injection in pre-filled pen	D712074	05-2024	10-2024
Mounjaro® 2.5mg KwikPen® solution for injection in pre-filled pen	D720751 D720957	09-2024	02-2025

There are no product quality, safety or efficacy concerns related to the affected Mounjaro® 2.5mg KwikPen® batches.
If needed, please reassure patients and caregivers that their medication can be taken and will continue to work safely and as intended until the end of the new expiry date.

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
- all suspected ADRs associated with new drugs and vaccines identified by the black triangle ▼

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/SystmOne/Vision/MiDatabank) for healthcare professionals
- free phone line: 0800 731 6789, Monday to Friday between 9am and 5pm

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.

Mounjaro® ▼ is subject to additional monitoring identified by the black triangle. Please continue to report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card Scheme.

To report adverse event information among patients taking Mounjaro, 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 Mounjaro. Please contact the Lilly Medical Information department if you have any question about the information in this letter or the safe and effective use of Mounjaro.
Sincerely,

Joanne Webb

Joanne Webb
Senior Medical Director
Eli Lilly and Company