Mounjaro®▼ (tirzepatide) KwikPen®

Initiation Support: Frequently Asked Questions (FAQs)

Indication

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:[1]

   - ≥ 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).

Adverse events and product complaints should be reported. Reporting forms and information can be found at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events and product complaints should also be reported to Lilly: please call Lilly UK on 01256 315 000.

Prescribing information can be found at the end of the document.

For healthcare professionals and relevant decision makers in Great Britain only
PP-TR-GB-0496 | June 2024

Lilly

once weekly mounjaro®▼ tirzepatide

Purpose of this Document

This document has been designed to support healthcare professionals and other relevant decision makers with responsibility for administration, consumption, prescription, purchase, recommendation, sale, supply of Mounjaro in private and NHS markets within Great Britain.

It is intended to provide reference information and troubleshooting guidance for this group to help support patients who have been initiated on Mounjaro. It is not intended to be made directly available for patients. **Patients should be advised to read the instructions for use and the package leaflet for the pre-filled KwikPen carefully before administering the medicinal product.**

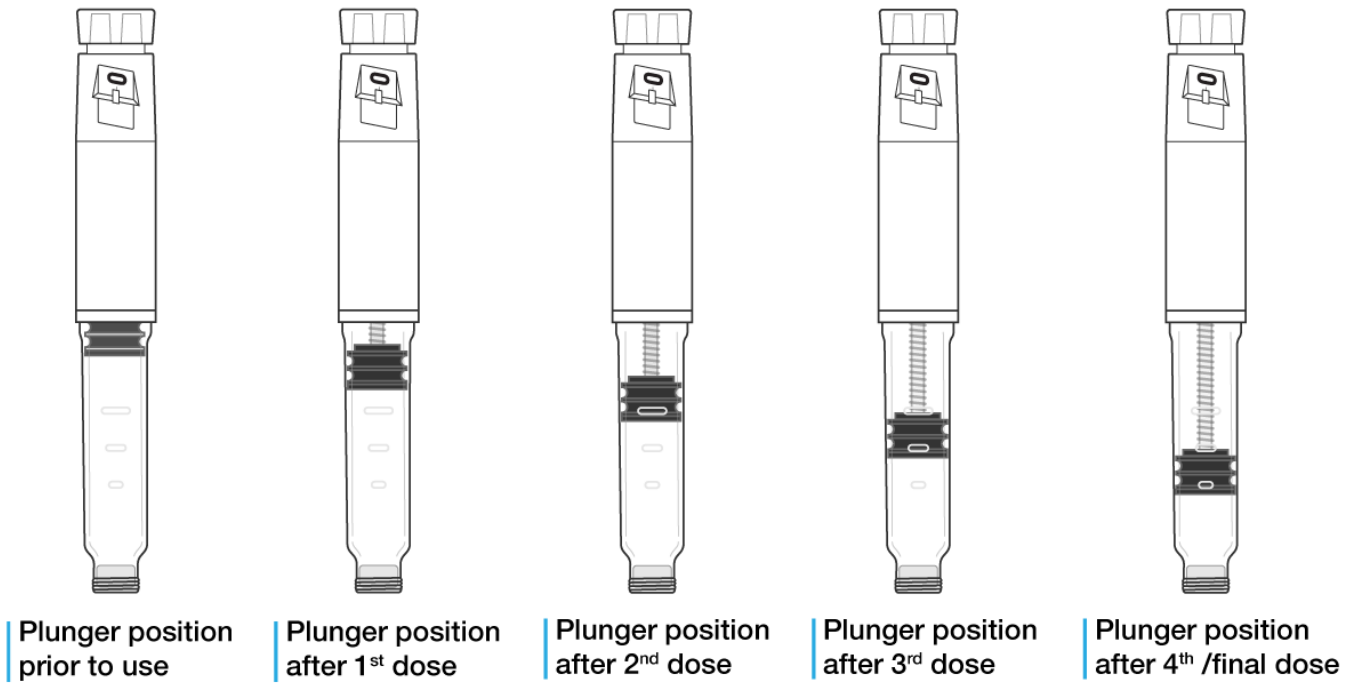
1. What volume of solution is injected for each dose, and how can this be observed on the KwikPen?

Each multi-dose pre-filled Mounjaro KwikPen contains 3 ml of solution. The KwikPen is designed to deliver 0.6 ml of tirzepatide per dose for a total of 4 doses. Each 0.6 ml dose contains the stated strength of tirzepatide on the carton labelling. For example, the Mounjaro® 2.5mg KwikPen contains 2.5mg of tirzepatide for each 0.6 ml dose. [1]

The multi-dose pre-filled KwikPen contains 2.4 ml (4 doses of 0.6 ml) of deliverable solution, with additional volume provided for priming of the device prior to each dose. After the fourth dose of tirzepatide is delivered, medication will remain in the KwikPen. **This is expected** (see image below). Users will be unable to dial an additional complete dose. The KwikPen and remaining solution should be discarded.

The image below illustrates the approximate plunger position and the medication volume left in the KwikPen after each dose is delivered.

The image shown is for illustrative purposes only:



2. Does the KwikPen come with needles? If not, what needles are appropriate to use?

The Mounjaro® KwikPen is not supplied with pen needles. Compatible pen needles, compliant with ISO 11608-2, must be used.

Needle compatibility:
The Mounjaro® KwikPen is compatible with ISO 11608-2 compliant pen needles from brands such as, BD, Novo Nordisk, and Terumo, in any length and gauge combination[2]:

- Lengths: 4 mm, 5 mm, 6 mm, 8 mm, 12.7 mm
- Gauges: 29G, 31G, 32G, 33G, 34G.[2]

Not all length and gauge combinations are commercially available. Patients should consult their healthcare provider for pen needle recommendations and guidance on proper injection technique.

ISO compliant and compatibility information may be found on pen needle packaging, manufacturer's website, or by contacting the manufacturer directly.

Needle length:
Tirzepatide supplied in the KwikPen should be administered via SC injection. Pen needles available for SC injection typically range from a length of 4 mm to 12.7 mm (5/32 inch to 1/2 inch).[2]

According to a review of the literature, pending availability of needle length, shorter needles are more appropriate and generally better tolerated. Pen needles of 4 mm are suitable for adult patients[3,4]

The decision on needle gauge and length remains at the discretion of the healthcare professional.

3. How can a user ensure 4 complete doses are delivered from the KwikPen?

Mounjaro KwikPen is a disposable multi-dose single-patient-use pre-filled pen. Each pre-filled KwikPen contains 2.4 ml (4 doses of 0.6 ml) of deliverable solution, with additional volume provided for priming of the device prior to each dose. Administration of the drug is once weekly enabling 4 doses (28-day supply) of medication from each device.

The KwikPen has been successfully primed if a small amount of medicine comes out of the tip of the pen needle. Users must adhere to the priming and dosing guidance in the Mounjaro® KwikPen Instructions For Use to ensure all 4 complete doses can be delivered.

Users may confirm that 4 doses have been delivered from the KwikPen by observing the plunger position. Following the delivery of the 4th dose of Mounjaro®, medication will remain in the KwikPen. **This is expected** (see earlier image). Even though medication remains in the pen, an additional complete 0.6 ml dose cannot be dialled. The KwikPen and remaining solution should be discarded.

4. What steps can a user take to prevent the KwikPen dose knob from being difficult to push?

To ensure the KwikPen functions as it should and to prevent the dose knob from being difficult to push or depress, the following should be considered in addition to the Patient Information Leaflet and Instructions for Use:

Injection Considerations:

- Prime the KwikPen before each injection to remove air from the cartridge and to ensure the pen is working correctly. Refer to the Instructions for Use for complete instructions on priming the KwikPen.
- If the dose knob is hard to press, push the dose knob down more slowly as this will make it easier to inject.

Proper Pen Needle Use:

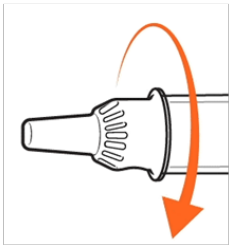
- Ensure that a new, KwikPen compatible pen needle is attached before each dose and that the pen needle is not damaged, bent, or broken. Confirm that the pen needle is securely attached creating a pathway for medication to flow properly. The dose knob may be difficult to push if the pathway is blocked by an obstructed pen needle.
- Never apply pressure to the dose knob without a pen needle attached as there is no pathway for the medication to flow. This will result in medication being wasted when a new needle is attached, possibly resulting in the inability to receive 4 full doses from the pen.

Proper Pen Storage:

- Store the KwikPen in an area that will prevent exposure to lint, dust, food, or liquid. The dose knob may become hard to push if these materials come in contact with the pen. If this occurs, the KwikPen should be discarded.
- Store in a refrigerator (2 ° C – 8 ° C). Do not freeze. Mounjaro may be stored unrefrigerated for up to 30 days at a temperature not above 30 ° C and then the pre-filled KwikPen must be discarded.[1]

5. What steps should be taken if the KwikPen dose knob is hard to push?

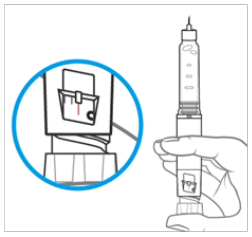
1. Attach a new pen needle to the KwikPen



2. Dial the KwikPen to the zero position “0”

3. Press the KwikPen dose knob

4. Prime the KwikPen as outlined in the Instructions For Use



If these steps are unsuccessful, a patient or HCP can contact UK Medical Information for support via 01256 315 000 or ukmedinfo@lilly.com

6. How can I report an issue with the KwikPen?

Adverse events and product complaints should be reported. Reporting forms and information can be found at UK: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events and product complaints should also be reported to Lilly: please call Lilly UK on 01256 315 000.

Specific product complaints should be reported to Lilly for investigation. This can be done by either HCPs or patients via the following routes:

- **Phone**: calling 01256 315 000, then press 1 after the automated intro
- **Email**: sending to ukmedinfo@lilly.com

The following steps set out the process for a product complaint after it has been submitted:

- Product complaint (PC) report received by Lilly Quality department, and a unique case ID is assigned for each case.

- Lilly Quality department work through standard investigation process, which has a 45-day timeline.
    - They may contact the clinician, patient, or Lilly team member as part of this process.
    - They may ask for the product to be returned for investigation – pre-paid envelopes are provided by Lilly for this purpose.

- If PC is upheld, it is passed to the Lilly supply team with the following options for replacement:
    - Free of cost replacement to same purchasing account.
    - Credit to purchasing account from invoice.

- If there is any evidence of user error, the PC is not upheld.

- A closure letter provided by Lilly for a specific investigation that contains a summary of findings and a conclusion can be requested at any time during this process.

References

1. Mounjaro® Kwikpen Summary of Product Characteristics.

2. Usach I, Martinez R, Festini T, Peris JE. Subcutaneous injection of drugs: literature review of factors influencing pain sensation at the injection site. *Adv Ther*. 2019;36(11):2986-2996.

3. Frid AH, Kreugel G, Grassi G, et al. New insulin delivery recommendations. *Mayo Clin Proc*. 2016;91(9):1231-1255.

4. Frid A, Hirsch L, Gaspar R, et al. New injection recommendations for patients with diabetes. *Diabetes Metab*. 2010;36(suppl 2):S3-S18.

Mounjaro® ▼ (KwikPen®) (tirzepatide)

PRESCRIBING INFORMATION United Kingdom (Great Britain)

This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. See section below for how to report adverse reactions. **Presentation:** Mounjaro solution for injection in a four-dose pre-filled pen containing 2.5 mg, 5 mg, 7.5 mg, 10 mg, 12.5 mg or 15 mg of tirzepatide in 0.6 ml solution. Each pre-filled Kwikpen contains 3 ml of solution. Mounjaro is a clear, colourless to slightly yellow solution. **Uses:** Type 2 diabetes. Mounjaro is indicated for the treatment of adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise either as monotherapy when metformin is considered inappropriate due to intolerance or contraindications, or in addition to other medicinal products for the treatment of diabetes. Weight management. Mounjaro is indicated 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). **Dosage and administration:** Posology: The starting dose of Mounjaro is 2.5 mg once weekly. After 4 weeks, the dose should be increased to 5 mg once weekly. If needed, dose increases can be made in 2.5 mg increments after a minimum of 4 weeks on the current dose. The recommended maintenance doses are 5, 10 and 15 mg. The maximum dose is 15 mg once weekly. When Mounjaro 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. When Mounjaro is added to existing therapy of a sulphonylurea and/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 sulphonylurea and insulin. A stepwise approach to insulin reduction is recommended. *For weight management,* if patients have been unable to lose at least 5 % of their initial body weight 6 months after titrating to the highest tolerated dose, a decision is required on whether to continue treatment, taking into account the benefit/risk profile in the individual patient. (See SmPC for full information). Method of administration: Mounjaro is to be injected subcutaneously in the abdomen, thigh or upper arm. The dose can be administered at any time of day, with or without meals. Injection sites should be rotated with each dose. If a patient also injects insulin, they should inject Mounjaro into a different injection site. (See SmPC for full information). Missed doses: If a dose is missed, it should be administered as soon as possible within 4 days after the missed dose. If more than 4 days have passed, skip the missed dose and administer the next dose on the regularly scheduled day. In each case, patients can then resume their regular once weekly dosing schedule. *Changing the dosing schedule:* The day of weekly administration can be changed, if necessary, as long as the time between two doses is at least 3 days. Special populations: *Elderly, gender, race, ethnicity or body weight:* No dose adjustment is needed. *Renal impairment:* No dose adjustment is required for patients with renal impairment including end stage renal disease (ESRD). Experience with the use of tirzepatide in patients with severe renal impairment and ESRD is limited. Caution should be exercised when treating these patients with tirzepatide. *Hepatic impairment:* No dose adjustment is required for patients with hepatic impairment. Experience with the use of tirzepatide in patients with severe hepatic impairment is limited. Caution should be exercised when treating these patients with tirzepatide. *Paediatric population:* The safety and efficacy of tirzepatide in children aged less than 18 years have not yet been established. No data are available. (see SmPC for full information) **Contra-indications:** Hypersensitivity to the active substance or to any of the excipients listed in the SmPC. **Special warnings and precautions:** *Acute pancreatitis:* Tirzepatide has not been studied in patients with a history of pancreatitis, and should be used with caution in these patients. Acute pancreatitis has been reported in patients treated with tirzepatide. Patients should be informed of the symptoms of acute pancreatitis. If pancreatitis is suspected, tirzepatide should be discontinued. If the diagnosis of pancreatitis is confirmed, tirzepatide 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. *Hypoglycaemia in patients with type 2 diabetes:* Patients receiving tirzepatide in combination with an insulin secretagogue (for example, a sulphonylurea) or insulin may have an increased risk of hypoglycaemia. The risk of hypoglycaemia may be lowered by a reduction in the dose of the insulin secretagogue or insulin. *Gastrointestinal effects:* Tirzepatide has been associated with gastrointestinal adverse reactions, which include nausea, vomiting, and diarrhoea. These adverse reactions may lead to dehydration, which could lead to a deterioration in renal function including acute renal failure. Patients treated with tirzepatide should be advised of the potential risk of dehydration, due to the gastrointestinal adverse reactions and take precautions to avoid fluid depletion and electrolyte disturbances. This should particularly be considered in the elderly, who may be more susceptible to such complications. *Severe gastrointestinal disease:* Tirzepatide has not been studied in patients with severe gastrointestinal disease, including severe gastroparesis, and should be used with caution in these patients. *Diabetic retinopathy:* Tirzepatide has not been studied in patients with non-proliferative diabetic retinopathy requiring acute therapy, proliferative diabetic retinopathy or diabetic macular oedema, and should be used with caution in these patients with appropriate monitoring. *Elderly:* Only very limited data are available from patients aged ≥ 85 years. *Sodium content:* This medicinal product contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium free'. *Benzyl Alcohol:* This medicine contains 5.4 mg Benzyl Alcohol [E1519] in each 0.6 ml dose. Benzyl alcohol may cause allergic reactions. Patients with hepatic or renal impairment should be informed of the potential risk of metabolic acidosis due to accumulation of benzyl alcohol over time. **Interactions:** Tirzepatide delays gastric emptying and thereby has the potential to impact the rate of absorption of concomitantly administered oral medicinal products. This effect, resulting in decreased C_{max} and a delayed t_{max}, is most pronounced at the time of tirzepatide treatment initiation. Based on the results from a study with paracetamol, no dose adjustments are expected to be required for most concomitantly administered oral medicinal products. However, it is recommended to monitor patients on oral medicinal products with a narrow therapeutic index especially at initiation of tirzepatide and following dose increase. The risk of delayed effect should also be considered for oral medicinal products for which a rapid onset of effect is of importance. *Paracetamol:* No dose adjustment of paracetamol is necessary when administered with tirzepatide. *Oral contraceptives:* No dose adjustment of oral contraceptives is required in women with normal BMI. There is limited information about the effect of tirzepatide on the pharmacokinetics and efficacy of oral contraceptives in women with obesity or overweight. Switching is advised to a non-oral contraceptive method, or add a barrier method of contraception upon initiating tirzepatide therapy (for 4 weeks) or after each dose escalation (for 4 weeks). **Fertility, pregnancy and lactation:** *Pregnancy:* Tirzepatide is not recommended during pregnancy and in women of childbearing potential not using contraception. If a patient wishes to become pregnant, tirzepatide should be discontinued at least 1 month before a planned pregnancy due to the long half-life of tirzepatide. Tirzepatide should not be used during pregnancy. *Breast feeding:* It is unknown whether tirzepatide is excreted in human milk. A risk to the newborn/infant cannot be excluded. *Fertility:* The effect of tirzepatide on fertility in humans is unknown, animal studies with tirzepatide did not indicate direct harmful effects with respect to fertility. (see SmPC for full information) **Effects on ability to drive and use machines:** Tirzepatide has no or negligible influence on the ability to drive or use machines. When tirzepatide is used in combination with a sulphonylurea or insulin, patients should be advised to take precautions to avoid hypoglycaemia while driving and using machines. (see SmPC for full information). **Undesirable Effects:** *Serious side effects:* Acute pancreatitis (uncommon ≥ 1/1 000 to < 1/100), anaphylactic reaction (rare ≥ 1/10 000 to < 1/1 000), angio-oedema (rare). *Frequency of other side effects:* Very common (≥ 1/10): Hypoglycaemia when used with sulphonylurea or insulin (type 2 diabetes), nausea, diarrhoea, constipation (weight management) vomiting (weight management). Common (≥ 1/100 to < 1/10): Hypersensitivity reactions, dizziness (weight management), hypotension related events (weight management), hypoglycaemia when used with metformin and SGLT2i (type 2 diabetes), decreased appetite (type 2 diabetes), abdominal pain, vomiting (type 2 diabetes), dyspepsia, constipation (type 2 diabetes), abdominal distention, eructation, flatulence, gastroesophageal reflux disease, hair loss (weight management), fatigue, injection site reactions, heart rate increased (type 2 diabetes), lipase increased, amylase increased (type 2 diabetes). Prescribers should consult the SmPC for further information in relation to other adverse reactions. *For full details of these and other side-effects, please see the Summary of Product Characteristics, which is available at http://www.medicines.org.uk/emc/.* **Legal Category:** POM **Marketing Authorisation Numbers (or Product Licence Numbers) and Holder:** PLGB 14895/0340, PLGB 14895/0341, PLGB 14895/0342, PLGB 14895/0343, PLGB 14895/0344, PLGB 14895/0345. Eli Lilly Nederland B.V. Papendorpseweg 83 3528 BJ Utrecht The Netherlands. **Cost (GB Only):** 1 x 2.5 mg pre-filled KwikPen: £92.00, 1 x 5 mg pre-filled KwikPen: £92.00, 1 x 7.5 mg pre-filled KwikPen: £107.00, 1 x 10 mg pre-filled KwikPen: £107.00, 1 x 12.5 mg pre-filled KwikPen: £122.00, 1 x 15 mg pre-filled KwikPen: £122.00. **Date of Preparation or Last Review:** 25 January 2024. **Further Information is Available From:** Eli Lilly and Company Limited, Lilly House, Basing View, Basingstoke, Hampshire, RG21 4FA. Telephone: **UK (Great Britain):** + 44-(0) 1256 315000, E-mail: ukmedinfo@lilly.com, Website: www.lilly.co.uk

INT-TR-GB-0196 January 2024

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