

Tirzepatide (Mounjaro®) for treating type 2 diabetes (T2DM) in adults. Prescribing Support Information for Primary Care.

This information is provided to support primary care clinicians prescribing Tirzepatide (Mounjaro®) for treating type 2 diabetes (T2DM).

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| Category | Tirzepatide is a long-acting GIP (glucose-dependent insulinotropic polypeptide) receptor and GLP-1 (glucagon-like peptide-1) receptor agonist that increases insulin sensitivity and secretion, suppresses glucagon secretion, and slows gastric emptying. |
| Therapeutic indications | An alternative to GLP-1 receptor agonists for the treatment of adults with insufficiently controlled type 2 diabetes (T2DM). |
| Pharmaceutical Form | <p>Tirzepatide is available in doses of 2.5mg, 5mg, 7.5mg, 10mg, 12.5mg and 15mg.</p> <p>Currently only available in the UK in the pre-filled disposable injection device (KwikPen®). Each KwikPen® device contains 2.4ml of solution (0.6ml per dose) and contains 4 doses of each specified strength.</p> <p>The KwikPen® packs do not contain needles. Prescribe screw -on pen needles for the pre-filled device separately.</p> |
| NICE Guidance and place in therapy | <p>NICE technology appraisal (TA) guideline NICE TA 924 Tirzepatide for treating type 2 diabetes (T2DM) recommends it as an alternative to GLP-1 receptor agonists for treating T2DM alongside diet and exercise in adults when it is insufficiently controlled only if:</p> <ul style="list-style-type: none"> • triple therapy with metformin and 2 other oral antidiabetic drugs is ineffective, not tolerated, or contraindicated, and • they have a body mass index (BMI) of 35 kg/m² or more (usually reduced by 2.5kg/m² for people from South Asian, Chinese, other Asian, Middle Eastern, Black African, or African-Caribbean family backgrounds), and specific psychological or other medical problems associated with obesity, or • they have a BMI of less than 35 kg/m² and: <ul style="list-style-type: none"> • insulin therapy would have significant occupational implications, or • weight loss would benefit other significant obesity-related complications. |
| Initiation and dosing advice | As with the GLP-1 agonists, tirzepatide can be initiated by Diabetes Specialist Teams or a General Practice Diabetes Specialist or healthcare professional (HCP) in GP Practice with relevant expertise and experience in management of |

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| | <p>type 2 diabetes(T2DM). The Integrated Community Diabetes Service [ICDS] or Integrated Diabetes Service [IDS] across BLMK can support with HCP training and education. Initiation should be in accordance with NICE recommendations and licensed indication. Refer to SPC.</p> <p>The starting dose of tirzepatide is 2.5 mg once weekly. After 4 weeks, the dose should be increased to 5 mg once weekly. If needed to achieve individual treatment goals, dose increases can be made in 2.5 mg increments after a minimum of 4 weeks on the current dose.</p> <p>The recommended maintenance doses are 5, 10 and 15 mg depending on individual tolerance. <i>(The 7.5mg and 12.5mg strengths are not licensed maintenance doses but for titration alone)</i>. The maximum licensed dose is 15 mg once weekly.</p> |
| Method of administration | <p>Tirzepatide 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.</p> <p>Patients should be advised to read the instructions for use included with the package leaflet carefully before administering the medicine.</p> |
| Missed Doses | <p>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.</p> <p><u>Changing the dosing schedule</u> The day of weekly administration can be changed, if necessary, as long as the time between two doses is at least 3 days.</p> |
| Monitoring and Continuation Criteria | <p>Like the GLP-1 agonists, tirzepatide should only be continued if the adult with type 2 diabetes(T2DM) has had a beneficial metabolic response (a reduction of at least 11 mmol/ mol [1.0%] in HbA1c and weight loss of at least 3% of initial body weight in 6 months). Consider discontinuing treatment if the response at 6 months is not maintained, taking into consideration the progressive nature of type 2 diabetes.</p> <p>At each review, check compliance, injection technique, injection site and discuss any possible side effects.</p> |
| Co-prescribing with other blood glucose lowering agents. | <ul style="list-style-type: none"> • When tirzepatide 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 tirzepatide is added to existing therapy of a sulphonylurea (SU) and/or insulin, a reduction in the dose of SU or insulin may be considered to reduce the risk of hypoglycaemia. Blood glucose self-monitoring is necessary to adjust the dose of SU and insulin. A stepwise approach to insulin reduction is recommended. • Like the GLP-1 agonists, combination therapy with tirzepatide and insulin should be on advice and guidance from the diabetes specialist teams with |

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| | ongoing support (when required) from community diabetes specialist teams or diabetes nurse consultant MDT. |
| Special Patient Population | <p>Elderly, gender, race, ethnicity, or body weight</p> <p>No dose adjustment is needed based on age, gender, race, ethnicity, or body weight.</p> <p>Renal impairment</p> <p>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.</p> <p>Hepatic impairment</p> <p>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.</p> <p>Paediatric population</p> <p>The safety and efficacy of tirzepatide in children aged less than 18 years have not yet been established. No data are available.</p> |
| Contraindications | Hypersensitivity to the active substance or to any of the excipients (see SPC for full details). |
| Cautions (see SPC for full details) | <ul style="list-style-type: none"> • Tirzepatide should be used with caution in patients with a history of pancreatitis. 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. • Gastrointestinal adverse reactions, which include nausea, vomiting, and diarrhoea have been reported with use. This may lead to dehydration which could lead to a deterioration in renal function including acute renal failure. Advise patients of potential risk of dehydration taking precautions to avoid fluid depletion and electrolyte imbalances. • Severe gastrointestinal disease, including severe gastroparesis. • Proliferative/non-proliferative diabetic retinopathy or diabetic macular oedema – appropriate monitoring is recommended. • Patients aged ≥ 85 years. |
| Adverse Effects (see SPC for full details) ▼ drug – report suspected | <ul style="list-style-type: none"> • Hypersensitivity reactions. • Hypoglycaemia when used with SU or insulin. • Gastrointestinal disorders e.g., nausea, diarrhoea, vomiting, abdominal pain etc. |

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| adverse effects to the MHRA | <ul style="list-style-type: none"> • Injection site reactions or pain. |
| Pregnancy, lactation and fertility | <ul style="list-style-type: none"> • 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 its long half-life. • A risk to the newborn/infant cannot be excluded. Shared decision must be made whether to discontinue breast-feeding or to discontinue/abstain from tirzepatide therapy taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman. • The effect of tirzepatide on fertility in humans is unknown. |
| Counselling Points | <ul style="list-style-type: none"> • Tirzepatide has no or negligible influence on the ability to drive or use machines. When tirzepatide is used in combination with a SU or insulin, patients should be advised to take precautions to avoid hypoglycaemia while driving and using machines. • Injection sites should be rotated with each dose. If a patient also injects insulin, they should inject tirzepatide into a different injection site. • Adequate hydration especially where GI adverse effects have been reported to prevent dehydration. |
| References | <ol style="list-style-type: none"> 1. Summary of product characteristics https://www.medicines.org.uk/emc/product/14205/smpc . Accessed 18/01/2024. 2. BNF https://bnf.nice.org.uk/drugs/tirzepatide/ Accessed 02/02/2024. 3. NICE Technology appraisal guidance [TA924]. Tirzepatide for treating type 2 diabetes. Published: 25 October 2023 https://www.nice.org.uk/guidance/ta924 . Accessed 18/01/2024. |

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