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# Mounjaro access in Saudi Arabia: the SFDA Personal Importation Program

How Saudi patients with type 2 diabetes obtain Mounjaro (tirzepatide) through the SFDA named-patient pathway, on-label only.

*Last reviewed 2026-05-12 by Reserve Meds clinical and regulatory team.*

## Quick orientation

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Mounjaro is the Eli Lilly brand of tirzepatide, the first-in-class dual GIP/GLP-1 receptor agonist administered by once-weekly subcutaneous injection. The US FDA approved Mounjaro on 13 May 2022 as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. The same molecule is marketed in the United States under a separate brand, Zepbound, with a distinct FDA approval for chronic weight management; the two products share an active ingredient but are labeled and packaged separately. Reserve Meds coordinates Mounjaro strictly on-label for type 2 diabetes. Patients seeking tirzepatide for weight management are out of scope on this page; Zepbound is the US obesity brand and is not within Reserve Meds' current scope. Mounjaro is registered with SFDA and listed in the Saudi Drug Information database, but local stocking has been uneven during the 2023 to 2025 demand surge. The SFDA Personal Importation Program (PIP) is the lawful route for a patient-specific import.

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## Why Saudi patients reach for Mounjaro through NPP

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SFDA registration of Mounjaro is established, but registration has not produced consistent on-shelf availability. Mounjaro and Zepbound were on the US FDA shortage list from December 2022 through October 2024, with formal reaffirmation of resolution in December 2024 and compounding transitions completing in February and March 2025. Allocation patterns during the shortage period were dose-strength specific: lower titration doses (2.5 mg, 5 mg) ran tighter at intervals, complicating new-patient starts, while higher maintenance doses (10 mg, 12.5 mg, 15 mg) were prioritised for continuing patients. International demand pressure persisted through the US shortage and into the post-shortage normalisation, driven in part by demand for the molecule as a weight-loss agent in jurisdictions where the obesity indication had not yet been registered. The cumulative effect in Saudi Arabia is stocking variability at the retail and hospital pharmacy level, even with SFDA registration in place.

The named-patient case in the Kingdom is therefore not unregistered access but continuity. A Saudi patient with documented type 2 diabetes, prior therapy history (typically metformin plus a second agent), and a stable Mounjaro regimen who loses access for several weeks risks meaningful glycemic instability. The PIP allows a treating endocrinologist or internist to import a specific quantity of the diabetes-labeled product for that named patient when local stock cannot meet the clinical timeline. Reserve Meds restricts intake to the FDA-approved type 2 diabetes

indication; any inquiry referencing obesity, weight management, or non-T2D use is declined or redirected at intake.

## **The SFDA Personal Importation Program for Mounjaro**

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The SFDA Personal Importation Program allows a Saudi-licensed physician to request import of a specific medicine for a specific named patient when the medicine is approved by a recognised reference authority and a clinically equivalent locally registered alternative is not suitable for that patient. Applications are filed through the dispensing institution's import pharmacy and reviewed by SFDA's Drug Sector through the Ghad digital platform.

For Mounjaro the clinical-justification angle is indication-specific and stocking-driven. A complete application typically includes:

- A clinical justification letter from the treating endocrinologist or internist naming the on-label indication (type 2 diabetes), the patient's HbA1c trajectory, prior therapy history (typically metformin plus a second agent), the documented Mounjaro regimen and dose, and the local stocking issue preventing continuity, with ICD-10 coding
- The treating physician's SCFHS license verification in endocrinology, diabetology, or internal medicine
- The patient identifier in SFDA's required format
- Product details: Mounjaro (tirzepatide) KwikPen, the specific dose strength (2.5 mg, 5 mg, 7.5 mg, 10 mg, 12.5 mg, or 15 mg per 0.5 mL), manufacturer Eli Lilly and Company, country of origin, pack size, quantity, lot, and expiry
- The destination dispensing facility license number for the SFDA-licensed pharmacy with validated refrigeration
- A cold-chain plan from the US authorised distributor through international transit with continuous temperature monitoring and excursion logging, including the 21-day room-temperature stability reserve for in-use storage

Approval timelines for routine cases (registered drug, clear on-label T2D indication, documented prior use) typically run 10 to 21 business days. Reserve Meds will not process Mounjaro requests where the diagnosis or prescription indicates obesity, weight management, or any non-T2D indication; such inquiries are redirected to the appropriate on-label channel or declined.

Mounjaro and Zepbound are not interchangeable from a labeling and prescription standpoint, even though the active ingredient is identical.

## **Where Mounjaro gets dispensed in Saudi Arabia**

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Mounjaro is stored at 2 to 8 degrees Celsius (refrigerated) in the original carton, protected from light. The dispensing footprint is the SFDA-licensed pharmacy network with validated refrigeration. Institutions that handle named-patient imports of injectable biologics as established practice include the diabetes and endocrinology services at King Faisal Specialist Hospital and Research Centre (KFSH&RC) in Riyadh and Jeddah; King Abdulaziz Medical City (KAMC) and the Ministry of National Guard Health Affairs network (MNGHA); the diabetes centers at Dr. Sulaiman Al Habib Medical Group (HMG) across Riyadh, Jeddah, and the Eastern Province; Saudi German Health endocrinology; Dr. Soliman Fakeeh Hospital in Jeddah; and Dallah Hospital in Riyadh. For private endocrinology clinics in Riyadh and Jeddah without

internal import infrastructure, the practical route is partnering with an SFDA-licensed specialty importer.

Once received, a Mounjaro KwikPen can be kept at room temperature up to 30 degrees Celsius for up to 21 days before first use; once held at room temperature it should not be returned to refrigeration. This 21-day room-temperature window provides operational flexibility for the patient at home, but the chain of custody from US release to Saudi receipt must remain refrigerated end to end.

## **Real cost picture for Mounjaro in Saudi Arabia**

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US wholesale acquisition cost for Mounjaro is approximately USD 1,069.08 per four-pen monthly carton, applied uniformly across all six dose strengths. Annualised, this equates to roughly USD 12,800 to USD 13,000 per year at WAC before any rebates or discounts. The Saudi riyal is pegged to the US dollar at approximately 3.75 SAR to 1 USD, so monthly US WAC translates to roughly SAR 4,010 per carton, with named-patient acquisition typically running modestly higher to cover authorised-distributor handling. The Reserve Meds firm quote is itemised: drug cost, international cold-chain logistics, SFDA permit handling, coordinator fee.

International cold-chain logistics for Mounjaro typically runs USD 800 to USD 1,500 per shipment (approximately SAR 3,000 to SAR 5,600), supported by validated refrigerated shippers, phase-change materials, and continuous temperature loggers. SFDA permit handling fees are nominal. On the insurance side, Bupa Arabia, Tawuniya, and MedGulf Arabia each assess named-patient imports case by case; coverage of GLP-1 and dual-incretin agents in T2D varies by plan. Reserve Meds supplies the documentation; the claim remains with you or your hospital.

## **Typical timeline for Mounjaro in Saudi Arabia**

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For an established Mounjaro patient with a clear on-label T2D clinical letter and a current prescription, the typical end-to-end cycle is 4 to 7 weeks. The SFDA PIP step generally runs 10 to 21 business days. US-side sourcing through an authorised distributor adds approximately 1 to 2 weeks, and validated cold-chain transit with Saudi customs clearance typically adds 3 to 5 days. The 21-day room-temperature stability window absorbs reasonable in-transit excursions but does not reset on receipt, so first-use timing in the patient's hands should follow the receiving pharmacy's dispensing date. Dose strength is locked at firm-quote issuance. Timelines are typical ranges, not promises.

## **What your physician needs to provide**

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The clinical justification letter for Mounjaro is the centrepiece of the SFDA package. For this product the letter typically includes:

- The patient's confirmed type 2 diabetes diagnosis with ICD-10 coding
- Prior therapy history, typically metformin plus a second agent, and the rationale for adding or continuing tirzepatide
- The documented Mounjaro regimen, dose, and titration history (2.5 mg starter for 4 weeks, then 5 mg maintenance, with escalation in 2.5 mg increments after a minimum of 4 weeks on the current dose, up to a maximum of 15 mg once weekly)
- The local stocking issue or continuity gap preventing access through the standard Saudi retail or hospital channel

- The monitoring plan: glycemic markers (HbA1c), renal function, signs of pancreatitis, gallbladder symptoms, progression of pre-existing diabetic retinopathy, hypoglycemia monitoring when combined with insulin or insulin secretagogues
- The contraindications acknowledgement: personal or family history of medullary thyroid carcinoma or Multiple Endocrine Neoplasia syndrome type 2 (boxed warning for thyroid C-cell tumors)
- The SFDA pharmacovigilance commitment for the full course of therapy

Any letter that references weight management, obesity, or a non-T2D indication is declined at Reserve Meds intake. Mounjaro and Zepbound are different US-labeled products and Reserve Meds sources only the diabetes-labeled product (Mounjaro).

## Common questions about Mounjaro in Saudi Arabia

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**Will Bupa Arabia, Tawuniya, or MedGulf cover Mounjaro?** Each insurer assesses named-patient imports case by case. Coverage of dual-incretin agents in T2D varies by plan; some require pre-authorization with the clinical justification letter attached. Reserve Meds does not promise coverage. We supply the documentation set that lets your insurer assess.

**Can Reserve Meds help me access tirzepatide for weight loss?** No. Reserve Meds coordinates Mounjaro strictly within the FDA-approved type 2 diabetes label. Zepbound is the US obesity brand of tirzepatide and is not within Reserve Meds' current scope. Patients seeking tirzepatide for weight management should consult their physician about the appropriate local pathway.

**Why Mounjaro versus Ozempic?** The SURPASS-2 trial published in NEJM in 2021 reported tirzepatide non-inferior and superior to once-weekly semaglutide 1 mg on HbA1c reduction in adults with type 2 diabetes. The choice between agents is a clinical decision for the prescriber, not Reserve Meds. Both are on-label for T2D in the United States.

**What is the safety profile?** Mounjaro carries a boxed warning for thyroid C-cell tumors and is contraindicated in patients with personal or family history of medullary thyroid carcinoma or MEN 2. Additional warnings cover pancreatitis, acute gallbladder disease (cholelithiasis, biliary colic, cholecystectomy reported in clinical trials), hypoglycemia when combined with insulin or secretagogues, acute kidney injury typically tied to volume depletion from severe GI adverse events, hypersensitivity reactions, severe GI disease, and diabetic retinopathy complications. The most common adverse reactions are gastrointestinal: nausea, diarrhea, decreased appetite, vomiting, constipation, dyspepsia, abdominal pain.

**Do I need to start at the lowest dose?** Yes. The label requires a 2.5 mg starter for 4 weeks for gastrointestinal tolerability, then 5 mg maintenance, with escalation in 2.5 mg increments after a minimum of 4 weeks on the current dose as additional glycemic control is needed. Titration is mandatory.

**Is the medicine self-administered at home?** Yes, after the receiving SFDA-licensed pharmacy has dispensed the KwikPen. Mounjaro is administered subcutaneously once weekly into the abdomen, thigh, or upper arm. The receiving pharmacy provides injection training or refers to the manufacturer's instructions.

## Where Reserve Meds fits in Mounjaro cases

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Reserve Meds is a US-based concierge coordinator. We do not replace your endocrinologist, do not replace SFDA, and do not replace the dispensing pharmacy. For Mounjaro specifically we orchestrate the US-side sourcing through an authorised distributor with DSCSA traceability, the regulatory documentation kit your physician needs (on-label T2D clinical letter template, titration reference, monitoring plan summary, SFDA pharmacovigilance reference), validated cold-chain logistics with continuous temperature logging, and a single named coordinator who carries the case from intake through quarterly refills. Reserve Meds will not process Mounjaro inquiries that reference weight management or non-T2D indications; those are redirected or declined at intake.

## Next step

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If your treating physician has documented your type 2 diabetes and local stocking is the bottleneck for your Mounjaro continuity, the named-patient pathway through SFDA is the route. Join the waitlist below and we will confirm eligibility within 24 to 48 hours and route the documentation kit to your physician.

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**Review & oversight.** Content on this page is reviewed by Reserve Meds's clinical and regulatory team. A US-licensed pharmacist reviews every prescription before dispensing. Regulatory posture is informational, not legal advice; case-specific questions route to retained outside counsel. [Review methodology >](#)  
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