Mounjaro access in India: the CDSCO Rule 36 named-patient pathway

How patients in India obtain Mounjaro (tirzepatide) on-label for type 2 diabetes through the CDSCO Rule 36 personal-import permit, with framing for the post-2025 Indian launch as a stocking-gap channel rather than a non-availability channel.

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

Quick orientation

Mounjaro is the Eli Lilly brand of tirzepatide, a once-weekly subcutaneous injection that is the first dual GIP/GLP-1 receptor agonist. The FDA approved Mounjaro in May 2022 as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes. Mounjaro received CDSCO import-and-marketing permission for type 2 diabetes and Eli Lilly launched Mounjaro commercially in India in 2025. Reserve Meds frames its Indian Mounjaro work as a stocking-gap channel for the post-launch period, not a non-availability channel: the product is registered and locally sold, and the named-patient route addresses the periods and pen presentations where local supply does not meet a patient's documented need on the timeline the clinician requires. Reserve Meds coordinates Mounjaro strictly for the on-label type 2 diabetes indication. The route is the CDSCO Rule 36 personal-import permit on Form 12A and Form 12B.

Reserved for you.

Why patients in India reach for Mounjaro through NPP

India faces three patterns of access gap for US originator specialty medicines: registered but not stocked, registered for a different indication, and not registered locally at all. Mounjaro in India sits firmly in the first pattern as of 2026. CDSCO granted Eli Lilly import-and-marketing permission for type 2 diabetes, and the commercial launch unfolded through 2025. The local registration is in place. The gap is supply continuity. During the 2023 to 2025 demand surge several jurisdictions saw inconsistent local availability of specific Mounjaro KwikPen dose strengths, particularly during titration windows and on higher maintenance doses. Indian patients with established Mounjaro prescriptions and clinical stability have looked for cross-border continuity when local stock runs short on the strength they need.

The framing matters. This is not a "Mounjaro is not available in India" page. Mounjaro is available in India. It is a stocking-gap page for the period when a local pharmacy cannot supply the specific KwikPen strength a patient's titration plan requires on the date the clinician requires. Reserve Meds coordinates only the on-label type 2 diabetes indication. Mounjaro and Zepbound (the obesity-indicated brand of tirzepatide) share the active ingredient but are labeled, packaged, and marketed separately. Patients seeking tirzepatide for weight management are out of scope for Mounjaro intake. Zepbound is out of Reserve Meds scope as of the current module date.

The CDSCO named-patient pathway for Mounjaro

The legal foundation for personal import of medicines into India is Rule 36 of the Drugs and Cosmetics Rules 1945. Rule 36 permits import of small quantities of a drug for the exclusive personal use of a named patient, even where local registration exists, when the local supply chain cannot meet that patient's documented need. Form 12A is the application for the permit. Form 12B is the permit itself, issued by the office of the Drugs Controller General of India (DCGI) at FDA Bhawan, Kotla Road, New Delhi, or by designated CDSCO Port Offices. The application is accompanied by a prescription from a Registered Medical Practitioner (RMP) showing the RMP's National Medical Commission registration number and the quantity required for treatment. The quantity of any single drug imported shall not exceed one hundred average doses per application.

For Mounjaro the clinical-justification angle is indication-locked and titration-specific. The Reserve Meds documentation kit asks the prescribing physician to confirm the on-label type 2 diabetes indication, to document HbA1c and the diabetes treatment history, to specify the KwikPen strength requested (2.5 mg, 5 mg, 7.5 mg, 10 mg, 12.5 mg, or 15 mg), and to confirm where the patient sits in the four-week titration sequence. The application typically includes:

- A clinical justification letter naming the type 2 diabetes diagnosis (with HbA1c), current treatment regimen (typically metformin plus a second agent), prior or current GLP-1 or dual-incretin exposure if any, and the reason the cross-border route is required (typically a documented local stocking gap on the specific KwikPen strength needed for the patient's current titration step)
- The treating physician's NMC registration number and a copy of state council registration where required
- A patient identifier and supporting medical records
- Product details: Mounjaro KwikPen, tirzepatide, the specified 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, quantity (not to exceed one hundred average doses per application)
- The dispensing facility's drug licence
- A chain-of-custody plan from an authorised US distributor under DSCSA to the dispensing pharmacy in India

CDSCO's published guidance states the Form 12B permit issues on a priority basis, typically within one to two days for routine applications where the documentation is complete. In practice patients plan for a two to four week window from physician decision to dispensed medicine, because the bulk of the elapsed time is upstream documentation assembly and downstream cold-chain logistics rather than the regulator stamp.

Where Mounjaro gets dispensed in India

Mounjaro is a refrigerated biologic-class injection in single-dose prefilled KwikPens. The dispensing facility must hold a valid drug licence and must be able to receive and store the product at 2 to 8 degrees Celsius. Tertiary endocrinology and diabetology services routinely handle this category. Institutions with established import-pharmacy and cold-chain infrastructure for refrigerated biologics include the All India Institute of Medical Sciences (AIIMS) in New Delhi, Apollo Hospitals (Chennai flagship, Delhi, Bangalore, Hyderabad, Kolkata) with dedicated diabetes and endocrinology programmes, Fortis Memorial Research Institute in Gurgaon and the Fortis Mulund, Bangalore, and Kolkata sites, Medanta in Gurgaon, Kokilaben Dhirubhai Ambani

Hospital in Mumbai, MGM Healthcare in Chennai, Christian Medical College (CMC) in Vellore, and Manipal Hospitals in Bangalore.

Patients managed by an endocrinologist or diabetologist outside a tertiary hospital typically route the import through a CDSCO-licensed specialty importer in Mumbai, Delhi, or Bangalore that handles the Form 12A filing, the customs broker, and the chain-of-custody documentation from the US authorised distributor to the dispensing pharmacy. Because Mounjaro is locally registered and locally launched, the dispensing footprint also includes the pharmacies in the Eli Lilly India distribution network for routine fills; the named-patient route applies when a specific KwikPen strength is not available locally.

Real cost picture for Mounjaro in India

US wholesale acquisition cost for Mounjaro is approximately USD 1,069 per four-pen monthly carton, applied uniformly across all six dose strengths, which annualises to roughly USD 12,800 to USD 13,000 per year at WAC before any rebates or insurer adjustments. Independent pricing aggregators report US cash retail prices in a similar band, with discount-card programmes reducing prices into the USD 800 to USD 950 range per month at select pharmacies; those programmes are US-only. International ex-US list prices vary by jurisdiction. The named-patient acquisition cost for India sits between US WAC and locally-discounted prices in markets like the United Kingdom and is finalised only on firm-quote issuance.

The Indian rupee floats against the US dollar. In May 2026 the USD/INR rate sits in the 94 to 95 range. Monthly drug acquisition at US WAC translates to roughly INR 100,000 per four-pen carton at the prevailing rate. International logistics for a refrigerated tirzepatide pen typically runs at USD 500 to USD 1,000 per shipment (approximately INR 47,000 to INR 95,000), inclusive of validated cold-chain packaging, temperature loggers, and the customs handover. India's Union Budget 2026-27 customs duty exemptions focus on cancer and rare-disease medicines; the specific HSN code and duty status for any Mounjaro shipment is confirmed at the documentation stage. GST on most life-saving medicines is 5%; other medicines fall in the 12% band.

On the insurance side, Star Health and Allied Insurance, HDFC ERGO, ICICI Lombard, and Niva Bupa handle named-patient imports case by case; none reimburse a Rule 36 personal import as a standard line item. Some have reimbursed full or partial drug cost where the underlying medicine is on their formulary and the import route was a stocking workaround; this is the configuration that most often applies to Mounjaro in India given the local registration. Mounjaro Savings Card and LillyDirect are US-only and do not apply to international named-patient sourcing.

Typical timeline for Mounjaro in India

For an established type 2 diabetes patient with documented diagnosis, current HbA1c, and a current Mounjaro prescription, the typical end-to-end cycle is 2 to 4 weeks. CDSCO published guidance puts the Form 12B priority window at 1 to 2 days for complete routine documentation. US-side sourcing through an authorised distributor adds roughly 1 to 2 weeks. International cold-chain transit and Indian customs clearance at Delhi, Mumbai, Bangalore, Chennai, or Hyderabad airport are typically 3 to 5 days inside the unopened-pen stability envelope. Mounjaro has a 21-day room-temperature stability window (up to 30 degrees Celsius before first use) that provides usable slack on transit; once a pen has been at room temperature, it should not be returned to refrigeration. Timelines are presented as typical ranges and not as promises; specific dates are confirmed at firm-quote issuance.

What your physician needs to provide

The clinical justification letter for Mounjaro is straightforward but indication-locked. For Reserve Meds intake the letter typically includes:

- Confirmation of the FDA-approved type 2 diabetes indication. Reserve Meds does not coordinate Mounjaro for any non-T2D indication. Patients with type 1 diabetes, gestational diabetes, or a history of pancreatitis are not Mounjaro candidates per the label
- Current HbA1c and the diabetes treatment history (metformin, sulfonylurea, DPP-4 inhibitor, SGLT-2 inhibitor, basal insulin, prior GLP-1 agonist if any)
- The requested KwikPen strength (2.5 mg, 5 mg, 7.5 mg, 10 mg, 12.5 mg, or 15 mg) and where the patient sits in the titration: starting dose 2.5 mg weekly for 4 weeks (not for glycemic control, tolerability only), then 5 mg, with 2.5 mg increments after a minimum of 4 weeks on the current dose up to a maximum of 15 mg weekly
- The screening for the boxed warning: confirmation that the patient does not have a personal or family history of medullary thyroid carcinoma or Multiple Endocrine Neoplasia syndrome type 2, and counselling on symptoms (neck mass, persistent hoarseness)
- The monitoring plan: pancreatitis vigilance (severe persistent abdominal pain), acute gallbladder disease (cholelithiasis, biliary colic), acute kidney injury particularly with severe GI adverse events causing volume depletion, hypoglycemia when used with insulin or sulfonylureas, diabetic retinopathy progression in patients with prior retinopathy
- The PvPI adverse-event reporting plan as part of the Pharmacovigilance Programme of India obligation

The treating physician's NMC registration number must appear on the prescription. State-council registration is required for practice in a particular state. Endocrinology and diabetology specialists at AIIMS, Apollo, Fortis, Medanta, Kokilaben, MGM, CMC Vellore, and Manipal routinely sign these letters as part of established institutional workflow.

Common questions about Mounjaro in India

Isn't Mounjaro available locally in India already? Yes. Mounjaro is registered with CDSCO and Eli Lilly launched Mounjaro commercially in India in 2025. The Reserve Meds named-patient route applies when the specific KwikPen strength a patient's titration plan requires is not available in the local pharmacy network on the date the clinician requires it. We frame this as a stocking-gap channel, not a non-availability channel.

I want Mounjaro for weight loss. Can you help? No. Reserve Meds coordinates Mounjaro only for its FDA-approved type 2 diabetes indication. Zepbound is the obesity-indicated brand of tirzepatide and is a separate product. Reserve Meds scope for Zepbound is separate from this Mounjaro pathway.

How do I know the Mounjaro you ship is authentic? Reserve Meds sources Mounjaro exclusively from US authorised distributors operating under the Drug Supply Chain Security Act (DSCSA). Every shipment carries DSCSA-compliant chain-of-custody documentation, lot and serial traceability, and continuous cold-chain temperature monitoring with data loggers in every parcel.

Will Star Health, HDFC ERGO, ICICI Lombard, or Niva Bupa cover Mounjaro? Each plan handles named-patient imports case by case. Some have reimbursed full or partial drug cost where the underlying medicine is on their formulary and the import was a stocking workaround; this is the typical Indian Mounjaro configuration given local registration. We supply the documentation set that lets your insurer assess the case. Cash-pay is the default posture.

What is the safety profile? The label carries a boxed warning for thyroid C-cell tumors based on rodent studies; human relevance is not established. Contraindicated in patients with personal or family history of medullary thyroid carcinoma or MEN 2. Additional warnings cover pancreatitis, acute gallbladder disease, hypoglycemia with insulin or sulfonylureas, acute kidney injury, hypersensitivity reactions, and diabetic retinopathy complications. Most common adverse reactions are gastrointestinal (nausea, diarrhea, decreased appetite, vomiting, constipation, dyspepsia, abdominal pain).

Mounjaro versus Ozempic, which is better? 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. Choice between agents is a clinical decision for the prescriber, not Reserve Meds. Both products are available through Reserve Meds for their respective on-label diabetes indications.

Where Reserve Meds fits in Mounjaro cases

Reserve Meds is a US-based concierge coordinator. We do not replace your endocrinologist, do not replace CDSCO, and do not replace the local Eli Lilly India distribution network or the dispensing pharmacy. For Mounjaro specifically we orchestrate the US-side sourcing through an authorised distributor under DSCSA, the regulatory documentation kit your physician needs for Form 12A (indication-locked letter template for T2D only, KwikPen strength reference, titration reference, boxed-warning screening checklist, monitoring plan summary, PvPI reporting reference), international cold-chain logistics with temperature loggers and validated 2 to 8 degrees Celsius packaging, and a single named coordinator who carries the case from intake through delivery. We coordinate Mounjaro strictly on-label for type 2 diabetes. Indian families looking for tirzepatide for weight loss are out of scope.

Next step

If your endocrinologist or diabetologist has decided Mounjaro is the right next step for type 2 diabetes and the specific KwikPen strength you need is not available locally on the timeline you require, the Rule 36 personal-import pathway through CDSCO 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.

Reserved for you.

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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