

[Skip to main content](#)

[Home](#) / [Drugs](#) / [Ozempic](#) / [In India](#)

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

How patients in India obtain Ozempic (semaglutide injection) on-label for type 2 diabetes, cardiovascular risk reduction, and chronic kidney disease, through the CDSCO Rule 36 personal-import permit, with DSCSA chain-of-custody documentation as the authenticity backbone.

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

Quick orientation

Ozempic is the Novo Nordisk brand of semaglutide injection, a once-weekly GLP-1 receptor agonist approved by the US FDA for adults with type 2 diabetes, for cardiovascular risk reduction in adults with type 2 diabetes and established cardiovascular disease, and most recently in January 2025 for reduction of kidney disease progression in adults with type 2 diabetes and chronic kidney disease. Ozempic holds CDSCO marketing authorisation in India, but local stock has been rationed throughout the 2022 to 2025 demand surge, and India has seen a large gray-market weight-loss demand running alongside legitimate diabetes prescribing. Reserve Meds is strict on-label for Ozempic. We coordinate Ozempic only for the three FDA-approved type 2 diabetes indications, with DSCSA chain-of-custody documentation from an authorised US distributor as the authenticity backbone against gray-market alternatives. 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 Ozempic 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. Ozempic sits in the first pattern. The product received CDSCO marketing authorisation and Novo Nordisk India staged commercial launch through 2024 and 2025, but on-shelf availability of specific pen presentations has lagged demand at retail in many Indian cities. Local supply has been routed preferentially to patients with established type 2 diabetes prescriptions, with periodic restrictions on new starts and intermittent stock-outs on specific pen strengths.

Parallel to the legitimate diabetes demand, India has a very large gray-market weight-loss demand for semaglutide. Multiple regulators and public-health bodies have warned about counterfeit and improperly handled semaglutide pens entering unauthorised channels. Reserve Meds is not part of that channel. We coordinate semaglutide only for the three on-label Ozempic indications (type 2 diabetes glycemic control, cardiovascular risk reduction in T2D with established cardiovascular disease, and reduction of kidney disease progression in T2D with chronic kidney disease per the January 2025 label expansion), with documented chain-of-custody from an authorised US distributor under the FDA's Drug Supply Chain Security Act framework. Patients seeking semaglutide for weight management are out of scope for Ozempic intake and are not redirected within the Reserve Meds workflow.

The CDSCO named-patient pathway for Ozempic

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. 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 Ozempic the clinical-justification angle is indication-specific. The Reserve Meds documentation kit asks the prescribing physician to name which of the three FDA-approved indications applies (T2D glycemic control, T2D plus established CVD for cardiovascular risk reduction, or T2D plus CKD for renal progression risk reduction), to document the diagnosis, to record the dose strength and pen presentation requested, and to confirm the standard 0.25 mg starting dose with 4-week titration steps. The application typically includes:

- A clinical justification letter naming the on-label indication, the diagnosis (with HbA1c reference for T2D, ASCVD documentation where applicable, eGFR and albuminuria where CKD applies)
- 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: Ozempic, semaglutide injection, the specified pen presentation (low-dose pen 0.25 mg or 0.5 mg per click, 1 mg pen, or 2 mg pen), manufacturer Novo Nordisk, 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 Ozempic gets dispensed in India

Ozempic is a refrigerated biologic-class injection in pre-filled disposable pens. 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 services and large hospital pharmacies 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, Tata Memorial Centre in Mumbai for patients carried under broader specialty care, 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. The importer carries the cold-chain validation; Reserve Meds aligns with the importer on US-side sourcing and with the prescribing physician on clinical documentation.

Real cost picture for Ozempic in India

US wholesale acquisition cost for Ozempic is approximately USD 997 per 30-day pen across the three pen presentations as of 2025, which equates to roughly USD 12,000 per year before any rebates, copay assistance, or insurance adjudication. Novo Nordisk announced a significant WAC reduction effective January 1, 2027, that would bring list price to roughly USD 675 per pen. International payer landscapes vary widely; public-sector prices in the European Union are generally negotiated below US WAC. Cash-pay pricing in India where the drug is registered but supply is constrained can equal or exceed US WAC depending on local agent margin.

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 94,000 per pen at the prevailing rate. International logistics for a refrigerated GLP-1 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 Ozempic shipment is confirmed at the documentation stage. GST on most life-saving medicines is 5%.

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. Manufacturer access programmes (NovoCare patient assistance, US copay savings) are US-only and do not extend to international patients. Cash-pay is the default posture. The Manufacturer Direct programme Novo Nordisk announced for US cash-pay patients does not apply outside the United States.

Typical timeline for Ozempic in India

For an established type 2 diabetes patient with documented diagnosis, current HbA1c, and a current Ozempic 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, with allocation to specific pen presentations (especially the 2 mg pen) sometimes tightening that window. 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, with the pen tolerating up to 56 days of room-temperature storage after first use. Reserve Meds plans the shipment so that cumulative cold-chain time at 2 to 8 degrees Celsius is preserved until the patient breaks the seal. 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 Ozempic is straightforward but indication-specific. For Reserve Meds intake the letter typically includes:

- The patient's confirmed type 2 diabetes diagnosis and which of the three on-label indications applies (T2D glycemic control as adjunct to diet and exercise; T2D with established cardiovascular disease for cardiovascular risk reduction; or T2D with chronic kidney disease for reduction of kidney disease progression and cardiovascular death)
- Current HbA1c and the diabetes treatment history (metformin, sulfonylurea, DPP-4 inhibitor, SGLT-2 inhibitor, basal insulin, prior GLP-1 agonist if any)
- For the CV-risk indication, documentation of established cardiovascular disease. For the CKD indication, the eGFR and albuminuria data that anchor the FLOW trial population
- The requested pen presentation (0.25 mg or 0.5 mg per click low-dose pen, 1 mg pen, or 2 mg pen) and the planned titration: 0.25 mg weekly for 4 weeks, then 0.5 mg weekly for at least 4 weeks, with further escalation to 1 mg and a maximum of 2 mg only as needed for glycemic control
- 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, dysphagia, persistent hoarseness)
- The monitoring plan: pancreatitis vigilance (severe persistent abdominal pain), acute kidney injury monitoring particularly with significant GI adverse events, retinopathy progression in patients with prior retinopathy, hypoglycemia monitoring when used with insulin or insulin secretagogues
- 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, diabetology, cardiology, and nephrology 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 Ozempic in India

I want Ozempic for weight loss. Can you help? No. Reserve Meds coordinates Ozempic only for its three FDA-approved type 2 diabetes indications. Patients seeking semaglutide for chronic weight management require the obesity-indicated product (Wegovy), not Ozempic. Off-label requests are declined at intake. The gray-market weight-loss channel for semaglutide carries documented authenticity and handling risks that we are not in a position to underwrite.

How do I know the Ozempic you ship is authentic? Reserve Meds sources Ozempic 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. This DSCSA chain is the central authenticity proposition compared with non-authorised channels.

Will Star Health, HDFC ERGO, ICICI Lombard, or Niva Bupa cover Ozempic? Each plan handles 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 the plan formulary and the import route was a stocking workaround. We supply the documentation set that lets your insurer assess the case. Cash-pay is the default posture.

Will CGHS cover Ozempic? CGHS provides for life-saving and approved medicines per the standard formulary, with non-formulary requests considered by an Expert Committee under Special DG (DGHS). Check eligibility with your CGHS Wellness Centre before assuming coverage.

What if the pen has been left out of refrigeration? Unopened Ozempic pens must be kept at 2 to 8 degrees Celsius. After first use a pen may be stored at room temperature up to 30 degrees Celsius or refrigerated, for up to 56 days. A pen that has been frozen at any point must be discarded.

What is the safety profile? The Ozempic label carries a boxed warning for thyroid C-cell tumors based on rodent carcinogenicity studies; human relevance is undetermined. Ozempic is contraindicated in patients with personal or family history of medullary thyroid carcinoma or MEN 2. Most common adverse reactions are gastrointestinal (nausea, vomiting, diarrhea, abdominal pain, constipation). The full safety profile is in the FDA prescribing information.

What about Mounjaro? Mounjaro (tirzepatide, Eli Lilly) is a dual GIP/GLP-1 agonist with FDA approval for type 2 diabetes. SURPASS-2 reported tirzepatide non-inferior and superior to once-weekly semaglutide 1 mg on HbA1c reduction. Choice between Ozempic and Mounjaro is a clinical decision for the prescriber.

Where Reserve Meds fits in Ozempic cases

Reserve Meds is a US-based concierge coordinator. We do not replace your endocrinologist, do not replace CDSCO, and do not replace the dispensing pharmacy or the licensed importer. For Ozempic specifically we orchestrate the US-side sourcing through an authorised distributor under DSCSA, the regulatory documentation kit your physician needs for Form 12A (indication-specific letter template, 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 Ozempic strictly on-label for the three FDA-approved type 2 diabetes indications. We do not coordinate Ozempic for weight management; that is what the Wegovy product is for, in a separate Reserve Meds workflow.

Next step

If your endocrinologist or diabetologist has decided Ozempic is the right next step and local stocking is the bottleneck, 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 >](#)

Last medically reviewed: 2026-05-12.