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

How families in India who care for an adult living with schizophrenia legally obtain Cobenfy (xanomeline and trospium chloride) from US-source supply, when the first new mechanism in psychiatry in three decades is not yet registered locally.

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

Quick orientation

Cobenfy (xanomeline and trospium chloride) is the first medicine in a new pharmacologic class for adult schizophrenia in more than three decades. The US Food and Drug Administration approved Cobenfy on 26 September 2024. Unlike every previously approved antipsychotic, Cobenfy does not block dopamine D2 receptors. It acts through selective muscarinic receptor activity in the brain, and the trospium component is included to blunt peripheral cholinergic side effects without entering the central nervous system. There is no public record of Cobenfy registration with the Central Drugs Standard Control Organization (CDSCO) as of this review. Patients in India whose treating psychiatrist judges Cobenfy to be the right next step reach the medicine through the CDSCO personal importation framework under Rule 36 of the Drugs and Cosmetics Rules 1945, with Form 12A application and Form 12B permit issued by the Drugs Controller General of India (DCGI), or through the institutional Compassionate Use route at hospitals such as AIIMS New Delhi and the psychiatric units of NIMHANS Bengaluru-affiliated tertiary centres. Reserve Meds coordinates US specialty-pharmacy sourcing, ambient international logistics, and the documentation kit your psychiatrist needs to file.

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Why patients in India need Cobenfy via the named-patient pathway

India has a deep mental-health infrastructure at the apex level. NIMHANS Bengaluru anchors national psychiatric care; the Department of Psychiatry at AIIMS New Delhi handles complex treatment-resistant cases; the Central Institute of Psychiatry Ranchi, the Institute of Human Behaviour and Allied Sciences (IHBAS) Delhi, and the psychiatric units at Apollo, Fortis, Medanta, Kokilaben, MGM Chennai, CMC Vellore, and Manipal Bangalore round out the tertiary tier. What is uniformly missing on the dispensing shelf is a muscarinic-class antipsychotic. Indian formularies in 2026 are dominated by the older D2-blocking agents (haloperidol, risperidone, olanzapine, quetiapine, aripiprazole, clozapine for the treatment-resistant cohort). Cobenfy is not yet locally registered; personal importation under Rule 36 is the legal route.

The clinical case for reaching across the border is mechanism-driven, not cost-driven. Every previously approved antipsychotic depends on dopamine D2 antagonism, and that dependency is the source of the side-effect profile that shapes long-term adherence: extrapyramidal symptoms, tardive dyskinesia, weight gain, metabolic syndrome, prolactin elevation, sedation. A subset of adults living with schizophrenia have cycled through two or three D2 antagonists and either cannot tolerate the burden or have not seen adequate response. Cobenfy enters the consideration set precisely for these patients. The conversation between a treating psychiatrist and the family of an adult patient who has been through multiple lines of conventional therapy is a serious one, and Cobenfy is now part of it. Reserve Meds approaches every Cobenfy inquiry with respectful, person-first language: patients living with schizophrenia, not "schizophrenics"; families navigating a chronic mental-health condition, not "cases".

The CDSCO Rule 36 named-patient pathway for Cobenfy

The legal foundation for personal import of an unregistered medicine into India is Rule 36 of the Drugs and Cosmetics Rules 1945. Rule 36 permits the import of a small quantity of a drug, whose import would otherwise be prohibited under Section 10 of the Drugs and Cosmetics Act 1940, 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 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 (NMC) registration number and the quantity required for treatment. The quantity of any single drug imported is capped at one hundred average doses per application, which for Cobenfy at twice-daily dosing fits a 50-day supply per filing.

For institutional Compassionate Use of drugs not approved for marketing in India at all, the parallel pathway is the Compassionate Use application route to the DCGI by a government hospital, a registered medical practitioner, a pharmaceutical company, or the patient. This route is used when the drug is approved by a recognised reference authority (FDA, EMA, MHRA, Health Canada, PMDA) for a serious permanent disability or an unmet medical need. Treatment-resistant or D2-intolerant schizophrenia fits the unmet-medical-need framing where the clinical record documents prior-line failure. AIIMS and other public-sector psychiatric centres have established Compassionate Use workflow.

For Cobenfy specifically, the clinical-justification angle in the Form 12A filing is the mechanism distinction. The strongest applications consistently document: a DSM-5 or ICD-11 diagnosis of schizophrenia with onset and course; the prior antipsychotic history, named drug by drug, with dates of trial, dose ranges achieved, response observed, and the reason for discontinuation (intolerance, inadequate response, contraindicating comorbidity); the specific clinical rationale for a non-D2-antagonist option; and the proposed titration plan following the FDA-labeled schedule (50 mg / 20 mg twice daily on days 1 to 2, 100 mg / 20 mg twice daily on days 3 to 7, then 125 mg / 30 mg twice daily from day 8 onward, with a step-back to 100 mg / 20 mg twice daily for tolerability). For geriatric patients the maximum recommended dose is 100 mg / 20 mg twice daily, which is noted in the letter where it applies. The monitoring plan includes baseline liver function tests and ongoing assessment per the label discontinuation criteria, blood pressure and heart rate tracking, and assessment for urinary retention particularly in male and older patients. CDSCO's published guidance states Form 12B is typically issued within one to two business days for routine applications where the documentation is complete.

Where Cobenfy gets dispensed in India

Cobenfy is an oral capsule taken twice daily. It does not require an infusion centre, a transfusion suite, or specialised monitoring infrastructure beyond what a tertiary psychiatric clinic already provides. The dispensing facility must hold a valid drug licence under the Drugs and Cosmetics Rules. The hospital outpatient pharmacy at NIMHANS Bengaluru, AIIMS New Delhi, the Central Institute of Psychiatry Ranchi, IHBAS Delhi, the psychiatric units of Apollo Hospitals (Chennai flagship, Delhi, Bangalore, Hyderabad, Kolkata), Fortis Memorial Research Institute Gurgaon, Medanta The Medicity Gurgaon, Kokilaben Dhirubhai Ambani Hospital Mumbai, MGM Healthcare Chennai, Christian Medical College (CMC) Vellore, and Manipal Hospitals Bangalore are typical dispensing points. Where the treating psychiatrist is in a smaller city, the practical pattern is to route through a CDSCO-licensed specialty importer in Mumbai, Delhi, or Bangalore that handles the documentation and chain-of-custody on behalf of the local clinic.

Direct-to-home delivery outside a licensed dispensing facility is not the model. The medicine is released from the hospital pharmacy or the licensed importer to the patient and family at the dispensing point, with the usual counselling on titration, food timing (capsules taken at least one hour before a meal or at least two hours after a meal), and the instruction not to open, crush, or chew the capsules.

Real cost picture for Cobenfy in India

Costs sit in Indian rupees with the rupee floating against the US dollar. In May 2026 the USD/INR rate is in the 94 to 95 range. Bristol Myers Squibb publishes a US wholesale acquisition cost (WAC) for Cobenfy of approximately USD 1,887 for a 30-day supply, which BMS frames as an annual cost of therapy of approximately USD 22,500. At the prevailing USD/

INR rate, the published US WAC converts to approximately INR 1.78 lakh per 30-day supply or INR 21.2 lakh per year, before any international logistics, documentation, or coordination is layered on. Cobenfy is the simplest possible international-logistics profile: oral capsules, room-temperature stable, no reconstitution, no cold-chain, no temperature data logger, standard ambient pharmaceutical cargo. International shipping for an ambient oral product to an Indian destination typically runs USD 200 to 500 per shipment (approximately INR 19,000 to 47,000) depending on city and consolidation. Reserve Meds itemises the US-side procurement, the international logistics, and the concierge coordination fee separately on every firm quote.

CDSCO permit fees are nominal. India's Union Budget 2026-27 customs-duty rules apply at the HSN-code level confirmed at the documentation stage. GST on most life-saving medicines is 5 percent. None of the major Indian private insurers (Star Health and Allied Insurance, HDFC ERGO, ICICI Lombard, Niva Bupa) reimburse a Rule 36 personal import of an unregistered psychiatric drug as a standard line item. CGHS may consider life-saving non-formulary medicines case by case under the Special DG (DGHS) Expert Committee route, with stricter constraints on drugs not approved by DCGI. The operating default is cash-pay. The Cobenfy Cares US patient support program (copay assistance, free trials) is US-only and does not extend to international named-patient orders.

Typical timeline for Cobenfy in India

For a routine Cobenfy case at an established psychiatric institution, the CDSCO Form 12B permit window is typically one to two business days from a complete Form 12A filing, per the regulator's published guidance. Because Cobenfy is room-temperature stable, the international transit window is the favourable ambient-cargo range (typically three to five business days from US specialty pharmacy dispatch to Indian customs clearance, depending on the destination port and the day of week). There is no temperature-monitored handoff, no validated cold-chain shipper to coordinate, and no excursion incident workflow. End-to-end, families typically plan for two to four weeks from psychiatrist decision to the first dispensed bottle, with the bulk of the elapsed time spent on upstream documentation assembly and US specialty-pharmacy intake rather than on the regulator's stamp or the flight. Once the first 30-day supply is in hand, the maintenance cadence is straightforward: 30-day or 90-day fills aligned to the once-a-trip family-coordination pattern.

What your physician needs to provide

The clinical justification letter is the cornerstone of the Form 12A filing. For Cobenfy, the strongest letters consistently include: a DSM-5 or ICD-11 diagnosis of schizophrenia with onset and current course; the documented antipsychotic history, listed by drug, with dates, dose ranges, observed response, and the reason each prior agent was discontinued; the specific clinical rationale for a non-D2-antagonist option (intolerance to D2 blockade, inadequate response on adequate trials of two or more D2 agents, or a contraindicating comorbidity such as significant tardive dyskinesia, severe metabolic adverse events, or prolactin-related effects that affected adherence); the proposed titration plan following the FDA-labeled schedule (50 mg / 20 mg twice daily on days 1 to 2, 100 mg / 20 mg twice daily on days 3 to 7, then 125 mg / 30 mg twice daily from day 8, with a step-back option to 100 mg / 20 mg for tolerability; geriatric maximum capped at 100 mg / 20 mg twice daily); a clear statement that the patient does not have moderate or severe hepatic impairment, which is a contraindication; the monitoring plan covering baseline liver function tests, ongoing assessment per the label discontinuation criteria (jaundice, pruritus, ALT greater than five times the upper limit of normal or five times baseline), blood pressure and heart rate, and urinary retention surveillance; and the prescribing psychiatrist's NMC registration number.

The patient identifier, the dispensing institution's drug licence, and the chain-of-custody plan from the US specialty pharmacy to the Indian dispensing pharmacy complete the file. The treating psychiatrist retains the clinical decision and the Pharmacovigilance Programme of India (PvPI) adverse-event reporting obligation. Reserve Meds includes the PvPI reference in the physician documentation kit; the reporting obligation itself stays with the prescribing physician.

Common questions about Cobenfy in India

Will Star Health, HDFC ERGO, ICICI Lombard, or Niva Bupa cover Cobenfy?

Each plan handles named-patient imports case by case. None of the major Indian private insurers reimburse a Rule 36 personal import of an unregistered psychiatric drug as a standard line item. Reserve Meds provides itemised documentation that lets the insurer evaluate. Cash-pay is the operating default.

Will my CGHS or ESIC entitlement cover Cobenfy?

CGHS provides for life-saving non-formulary medicines to be considered by an Expert Committee under Special DG (DGHS) case by case, where the prescribing specialist documents the clinical requirement. Drugs not approved by the DCGI for use in India face a stricter Expert Committee review. ESIC's formulary is narrower. Neither scheme is structured for routine personal-import reimbursement of a launch-window novel-mechanism psychiatric drug. Confirm eligibility with your CGHS Wellness Centre or ESIC dispensary before assuming coverage.

What is the safety profile families should be aware of?

In the EMERGENT program the most frequent adverse events were gastrointestinal: nausea, dyspepsia, constipation, vomiting, abdominal pain, diarrhoea, gastroesophageal reflux. Cardiovascular signals included hypertension and tachycardia. Most gastrointestinal events were mild or moderate and generally transient. The drug avoids the extrapyramidal, tardive dyskinesia, weight gain, and prolactin signals associated with D2-blocking antipsychotics. The label includes a labeled risk of bile duct obstruction, gallstones, pancreatitis, and liver enzyme elevation, and clinicians monitor accordingly. Urinary retention is monitored particularly in male and older patients. The treating psychiatrist reviews the full label with the family before initiating therapy.

Is there a competitor or alternative at the muscarinic mechanism level?

At the muscarinic mechanism level, no FDA-approved alternative exists. Other muscarinic-acting compounds are in clinical development. All conventional alternatives are D2 antagonists. The treating psychiatrist owns the choice between continuing on a D2 agent, trialling clozapine (the established treatment-resistant option), or reaching for Cobenfy via personal importation.

What is the typical course duration?

Schizophrenia is a chronic condition. Cobenfy is dosed continuously, not for a defined course. Discontinuation decisions are made on the same clinical basis as discontinuation of any maintenance antipsychotic, by the treating psychiatrist in consultation with the patient and family.

Is Cobenfy a controlled substance?

No. Cobenfy is not a DEA-scheduled drug. It is in scope for Reserve Meds personal-importation coordination, and is not subject to the additional Narcotics Control Bureau workflow that controlled substances require.

Where Reserve Meds fits in Cobenfy cases

Reserve Meds is a US-based concierge coordinator. We do not replace your psychiatrist, do not replace CDSCO or the DCGI, and do not replace the dispensing hospital pharmacy or the licensed specialty importer. What we do is orchestrate US specialty-pharmacy sourcing of FDA-labeled product through BMS-authorised channels with DSCSA-compliant serialisation, ambient international logistics, and the documentation kit your psychiatrist needs for the Form 12A filing. Operationally Cobenfy is among the most forgiving products we coordinate: small molecule, room-temperature, oral, no REMS, no cold-chain. The work lives in documentation precision and in the family-coordination layer that long-term

psychiatric care demands. A single named coordinator carries the case from intake through the titration window and into the maintenance cadence, with the same coordinator on the file across multi-city, multi-country family configurations. No prior Reserve Meds closed case experience exists for Cobenfy in India as of this review; standard NPP coordination applies, with particular attention to family communication around a stigmatised diagnosis.

Next step

If an adult patient in India is living with schizophrenia and the treating psychiatrist is now considering a non-D2-antagonist option after prior-line failure, add the case to the waitlist. We will respond within 24 to 48 hours with a documentation kit for your psychiatrist and an indicative cost range.

Reserved for you.
