Ravicti access in India through the CDSCO Rule 36 Form 12A pathway

How Indian families managing a pediatric urea cycle disorder source Ravicti (glycerol phenylbutyrate) for chronic outpatient nitrogen-scavenger therapy, what the Form 12A application package looks like, and where Reserve Meds fits.

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

Quick orientation

Ravicti is the brand name for glycerol phenylbutyrate, a room-temperature stable oral liquid pre-prodrug used in the chronic outpatient management of urea cycle disorders (UCDs) in adults and pediatric patients aged 2 months and older who cannot be managed by dietary protein restriction or amino acid supplementation alone. The US FDA first approved Ravicti on 1 February 2013, with subsequent label extensions adding neonatal use. CDSCO does not list Ravicti as a registered product in India as of this page date. An Indian family with a molecularly confirmed UCD diagnosis can reach Ravicti lawfully through Rule 36 of the Drugs and Cosmetics Rules 1945, prescribed by an NMC-registered metabolic geneticist or pediatric specialist and dispensed through a hospital pharmacy or a CDSCO-licensed specialty importer. Reserve Meds coordinates the US-side sourcing and the documentation kit your physician needs to file the Form 12A application. Reserved for you.

Why Indian families need Ravicti through the named-patient pathway

Urea cycle disorders are ultra-rare, with an estimated combined incidence below 1 in 35,000 live births. Local commercial registration is uneconomic in many smaller national markets, and manufacturer prioritisation skews to the largest reference markets. The structural access pattern in India sits in the third of the three patterns the country module describes: the drug is FDA-approved (and EMA-approved since 27 November 2015) but Horizon Therapeutics, now an Amgen subsidiary following the 6 October 2023 acquisition, has not pursued CDSCO marketing authorisation. Indian families with a UCD-affected infant or child typically have a confirmed enzyme-defect diagnosis through AIIMS New Delhi's medical genetics service, CMC Vellore, or another tertiary metabolic genetics programme, with no locally registered nitrogen-scavenger oral liquid to offer as chronic outpatient therapy.

UCDs typically present in the neonatal or early pediatric period, and therapy is lifelong. A family with a UCD diagnosis must source the product continuously, year after year, for the life of the child. The chronicity of the need amplifies the cost and operational burden of any local gap. The alternatives inside the Indian market are limited. Sodium phenylbutyrate (Buphenyl) is also rarely registered, sodium benzoate and sodium phenylacetate formulations are inpatient agents for acute hyperammonaemia rather than chronic management, and liver transplantation is a separate and very different decision pathway. Rule 36 was designed for exactly this situation: an FDA-approved medicine, no clinically equivalent locally registered alternative, and a serious chronic condition where the treating physician documents the specific reason this product is required.

The CDSCO Rule 36 personal import pathway for Ravicti

The legal foundation for personal import of unregistered medicines into India is Rule 36 of the Drugs and Cosmetics Rules 1945. Rule 36 permits import of small quantities 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; Form 12B is the permit, 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. CDSCO published guidance states the Form 12B permit is issued on a priority basis, typically within one to two days for routine applications where the documentation is complete.

For Ravicti specifically, the clinical-justification angle that anchors the Form 12A application is pediatric metabolic confirmation. Ravicti is approved only for chronic management of urea cycle disorders. The application is strongest when the metabolic geneticist's letter sets out (1) the molecular genetic or biochemical confirmation of the specific UCD subtype (OTC deficiency, CPS1 deficiency, ASS1 / citrullinemia, ASL / argininosuccinic aciduria, ARG1 / argininemia, NAGS deficiency, or HHH syndrome) with the reporting laboratory named, (2) the current weight and body surface area to support weight-banded dosing, (3) current plasma ammonia and the recent metabolite panel including plasma glutamine and branched-chain amino acids, (4) the dietary protein prescription that Ravicti is intended to supplement, (5) prior therapy if the patient is transitioning from sodium phenylbutyrate (Buphenyl), and (6) the planned plasma-ammonia titration target (fasting ammonia below half the upper limit of normal in patients aged 6 years and older; age-appropriate morning ammonia target in infants and younger children).

A complete Form 12A application includes a clinical justification letter from the treating Registered Medical Practitioner, the prescription showing the RMP's NMC registration number and the quantity required for treatment, a patient identifier with supporting medical records, product details (Ravicti as glycerol phenylbutyrate oral liquid, 1.1 g/mL strength in 25 mL multi-dose glass bottles, manufacturer Horizon Therapeutics USA / Amgen, requested quantity not exceeding 100 average doses per application per the second proviso to Rule 36), the dispensing facility's drug licence, and a chain-of-custody plan from the US specialty pharmacy through the importer to the receiving Indian pharmacy. For Compassionate Use of a drug not approved for marketing in India at all, the parallel route is a Compas