

Crenessity

India · access guide

Crenessity access in India: the CDSCO Rule 36 pathway

Last reviewed 2026-05-16 by Reserve Meds clinical and regulatory team.

Quick orientation

Crenessity (crinecerfont) is an oral selective corticotropin-releasing factor type 1 (CRF1) receptor antagonist approved by the US Food and Drug Administration in December 2024 for the treatment of classic congenital adrenal hyperplasia in adults and pediatric patients 4 years of age and older. The product, manufactured by Neurocrine Biosciences, addresses the long-standing therapeutic gap in classic CAH: patients have historically required supraphysiologic doses of glucocorticoids to suppress excess adrenal androgen production, with chronic high-dose steroid exposure causing growth suppression, cushingoid features, osteoporosis, and metabolic syndrome. Crenessity reduces the upstream ACTH drive on the adrenal cortex, allowing physicians to lower glucocorticoid doses to physiologic replacement while still controlling androgen excess. The CAHtalyt Adult and Pediatric pivotal trials reported significant reductions in androstenedione, 17-hydroxyprogesterone, and required glucocorticoid dose. Crenessity is not yet registered with India's CDSCO, and access for Indian patients runs through the Rule 36 personal-import pathway.

Why Indian patients ask about Crenessity

India has a substantial CAH patient population given the country's overall scale, and pediatric endocrinology programs at AIIMS Delhi, AIIMS Rishikesh, PGIMER Chandigarh, CMC Vellore, KEM Mumbai, NIMS Hyderabad, Sanjay Gandhi Postgraduate Institute Lucknow, Madras Medical College Chennai, and the private network (Apollo, Fortis, Manipal, Kokilaben, Medanta) actively manage these patients across the pediatric-to-adult transition. The therapeutic rationale for Crenessity is especially compelling in pediatric patients whose growth trajectory has been compromised by chronic high-dose hydrocortisone, or in adults with cushingoid morbidity from long-term supraphysiologic prednisone. With FDA approval in December 2024, Indian families with endocrinologists tracking the literature have begun asking about access ahead of any CDSCO registration filing.

The CDSCO Rule 36 pathway for Crenessity

The legal foundation for import is Rule 36 of the Drugs and Cosmetics Rules 1945, which permits import of a small quantity of a drug whose import would otherwise be prohibited, for the exclusive personal use of a named patient. Form 12A is the application; Form 12B is the permit issued by the Drugs Controller General of India. The application requires a prescription from a Registered Medical Practitioner with NMC registration. For Crenessity, the Form 12A justification rests on the FDA approval, the inability to control adrenal androgens at physiologic glucocorticoid doses, or documented complications of supraphysiologic steroid exposure.

A complete application includes the clinical justification letter from the treating pediatric or adult endocrinologist, the physician's National Medical Commission registration, the patient identifier, the product details (Crenessity, crinecerfont, Neurocrine Biosciences, the strength matched to age and weight, quantity covering 90 days), and the receiving Importer of Record. Form 12B permits routinely issue on a 1-to-2 business day priority timeline per CDSCO's published procedure.

Where Crenessity is dispensed in India

Tertiary pediatric endocrinology centers handling classic CAH cases include AIIMS Delhi, PGIMER Chandigarh, CMC Vellore, KEM Hospital and Seth GS Medical College Mumbai, Madras Medical College and Government Hospital for Sick Children Chennai, Sanjay Gandhi Postgraduate Institute Lucknow, NIMS Hyderabad, BLDE University Vijayapura, and the major private hospitals (Apollo, Fortis, Manipal, Kokilaben, Medanta). Adult endocrinology programs at the same institutions handle the transition-aged and adult patient cohorts. Crenessity is an oral capsule and does not require cold-chain handling. The dispensing pharmacy is the prescribing hospital's outpatient pharmacy or a CDSCO-licensed specialty importer in Mumbai, Delhi, Bangalore, or Chennai.

Real cost picture for Crenessity in India

US wholesale acquisition cost for Crenessity is approximately USD 50,000 per year at adult full dosing (100 mg twice daily), with pediatric dosing weight-banded and pricing scaled accordingly. The Indian rupee trades at approximately 83 to 95 INR to 1 USD, so the annual reference range converts to roughly INR 41 lakh to INR 47 lakh at adult dosing. Pediatric dosing reduces the absolute cost. International logistics for oral medicines runs USD 200 to USD 500 per shipment quarter. CDSCO permit fees are nominal.

Typical timeline for Crenessity in India

End-to-end, most Indian Crenessity cases complete within 2 to 4 weeks from physician decision to dispensed product. Form 12B priority issuance runs 1 to 2 business days. Documentation assembly takes 3 to 5 business days. US-side sourcing and shipment runs 7 to 14 days. Refill cadence aligns to a quarterly reorder rhythm.

What your physician needs to provide

For an Indian pediatric or adult endocrinologist prescribing Crenessity, the clinical justification letter documents the classic CAH diagnosis confirmed by genetic testing or biochemical workup, the current glucocorticoid regimen and its limitations, the growth trajectory in pediatric patients, the patient's age and weight for dose calculation, and the planned monitoring schedule. The physician's National Medical Commission registration number completes the package.

Common questions about Crenessity in India

Will Star Health, HDFC ERGO, ICICI Lombard, or Niva Bupa cover this? Each Indian private insurer assesses named-patient imports case by case. None of the major private insurers reimburse Rule 36 personal imports as a standard line item. Some have reimbursed full or partial drug cost where the underlying medicine is on the formulary; for Crenessity, the post-approval window is short and formulary status will evolve.

Will my CGHS or ESIC entitlement cover this? CGHS provides for life-saving and rare-disease medicines not in the standard formulary case by case through an Expert Committee. For Crenessity, the expectation is that Expert Committee review would be required.

Is this only for pediatric patients? No. The FDA label covers adults and pediatric patients 4 years and older.

Can my child stop steroids entirely? No. Patients with classic CAH require glucocorticoid replacement for life. Crenessity allows the dose to be lowered from supraphysiologic suppressive doses toward physiologic replacement.

What about sick-day rules? Standard CAH sick-day rules continue: stress-dose glucocorticoids during illness, surgery, or trauma. Crenessity does not eliminate the need for sick-day steroid increases.

Where Reserve Meds fits in Crenessity cases

Reserve Meds is a US-based concierge coordinator. For Crenessity cases originating in India, we orchestrate US-side sourcing through DSCSA-compliant channels, build the Form 12A documentation packet your endocrinologist submits, coordinate shipment to the receiving Indian importer, and assign a single named coordinator. No prior Reserve Meds Crenessity case experience is logged yet at the India-origin profile.

Reserve Meds's role

US-based concierge coordinator for cross-border specialty medicine. We are not the prescriber, not the dispensing pharmacy, and not the manufacturer. All clinical decisions remain with your treating physician.

Reserve Meds

reserved for you.

Composite case examples. This document is for general information only and does not constitute medical advice. Please consult your treating physician.

Reserve Meds is in pre-launch. Published timelines and cost ranges are indicative, not guarantees.
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