

[Skip to main content](#)

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

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

How families in India legally obtain Agamree (vamorolone) for pediatric Duchenne muscular dystrophy from US or EU source supply through CDSCO personal importation, with weight-based dosing logistics and ambient-temperature handling built into the case plan.

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

Quick orientation

Agamree (vamorolone) is a first-in-class dissociative steroidal anti-inflammatory drug developed as an alternative to prednisone and deflazacort in Duchenne muscular dystrophy (DMD). It is formulated as an oral suspension at 40 mg per millilitre and was approved by the US Food and Drug Administration on 26 October 2023 for DMD in patients 2 years of age and older, with European Commission approval following in December 2023 and a CHMP positive opinion to expand the EU label down to age 2 issued on 27 April 2026. India has a very large DMD patient population by absolute numbers, and pediatric neuromuscular centres at AIIMS, Christian Medical College Vellore, Kokilaben, and Apollo Chennai regularly identify boys for whom families want the corticosteroid-class agent with the better bone, growth, and behaviour profile than prednisone or deflazacort. Agamree is not registered in India as of this review, and Indian families with cash means reach it through the Central Drugs Standard Control Organization (CDSCO) personal importation framework under Rule 36 of the Drugs and Cosmetics Rules 1945, with the Form 12A application and Form 12B permit issued by the office of the Drugs Controller General of India (DCGI). Reserve Meds coordinates the US-side or EU-side specialty sourcing through Catalyst Pathways or Santhera's local agent network, ambient-temperature logistics with no-freeze handling, and the documentation kit your pediatric neuromuscular specialist needs to file.

Reserved for you.

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

India has the largest DMD patient population of any Reserve Meds priority country by absolute numbers, with prevalence estimates frequently cited in the tens of thousands of boys. Pediatric neuromuscular care has matured substantially over the last decade at AIIMS New Delhi, Christian Medical College Vellore, Kokilaben Dhirubhai Ambani Hospital Mumbai, Apollo Hospitals Chennai, Manipal Hospitals Bangalore, and at the Centres of Excellence designated under the National Policy for Rare Diseases (NPRD) 2021. What India lacks for Agamree specifically is a local marketing authorisation. As of this review, vamorolone is not on the CDSCO register. A family that walks into a hospital pharmacy with an Agamree prescription cannot fill it, regardless of the prescribing neuromuscular specialist's institution.

The clinical reason families pursue Agamree rather than continuing on prednisone or deflazacort is the bone-growth-behaviour gradient. The VISION-DMD (VBP15-004) pivotal trial and its 48-week extension reported that switching from prednisone to vamorolone reversed growth stunting

seen during prior prednisone exposure, with fewer effects on linear growth, bone turnover, and behavioural side effects than the older corticosteroid-class agents. Families with a son already on years of prednisone, watching the trade-off play out between motor function preservation and the bone and behavioural costs, often want to make the switch even when standard corticosteroids are locally available and affordable. The clinical decision sits with the pediatric neuromuscular specialist; the procurement mechanism is Rule 36.

India's NPRD 2021 framework lists DMD as a Group 3a rare disease eligible for one-time financial assistance under the Rashtriya Arogya Nidhi umbrella scheme up to INR 50 lakh per patient. The ceiling is meaningful for some pediatric cohorts but is widely understood by treating clinicians and families to fall short of the indefinite annual cost of corticosteroid-alternative therapy at originator pricing, and NPRD support has not been the operating financial structure for routine Agamree cases. Diaspora-funded care is the more common pattern. An adult sibling in Dubai, Doha, London, or New Jersey paying the invoice for a younger brother in Hyderabad, Bengaluru, or Kochi is a configuration the Rule 36 framework accommodates when the named patient is the Indian resident child.

The CDSCO Rule 36 named-patient pathway for Agamree

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.

For Agamree specifically, the clinical-justification angle in a Form 12A application is the bone-growth-behaviour rationale that distinguishes vamorolone from prednisone and deflazacort. The strongest applications consistently include a pediatric neuromuscular specialist's confirmed diagnosis of DMD with genetic confirmation (dystrophin gene mutation result) or muscle biopsy result documented; the child's current weight and weight-adjusted Agamree dose at 6 mg/kg per day (with the dose recalculation schedule planned every 3 to 6 months as the child grows); the prior corticosteroid history if the patient is switching from prednisone or deflazacort, with the documented clinical rationale (growth stunting, bone density concerns, behavioural side effects); and the monitoring plan covering adrenal suppression risk during illness or stress, growth and bone health, blood pressure, serum potassium, and vaccination status (with live vaccines flagged as contraindicated during therapy).

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 applies when the drug is approved by a recognised reference authority (FDA, EMA, MHRA, Health Canada, PMDA) for an unmet medical need. Vamorolone qualifies under FDA and EMA approval. Government institutions including AIIMS New Delhi have established workflow for this pathway in pediatric rare-disease cases. CDSCO's published guidance states Form 12B is typically issued within one to two days for routine applications where documentation is complete. Indian families and hospitals plan for a two to four week window from physician decision to

dispensed medicine, because the bulk of elapsed time runs through upstream documentation assembly and downstream international logistics rather than the regulator's stamp.

Where Agamree gets dispensed in India

Agamree is an oral suspension. Dispensing capability is therefore broader than for an infusion biologic, but the dispensing facility must hold a valid drug licence covering imported unregistered medicines, must have refrigeration-optional ambient storage at 20 to 25 degrees Celsius (Agamree does not require refrigeration and freezing must be avoided), and must have a pediatric pharmacy desk capable of family training on the 100 mL bottle, the calibrated oral dosing syringe, and the requirement to shake vigorously before each dose. Once opened, the bottle is stable for 3 months at room temperature, which aligns with the weight-based recalculation cadence.

Indian institutions with established pediatric neuromuscular programmes and the pharmacy infrastructure for imported orphan medicines include AIIMS New Delhi (apex public-sector institution, designated NPRD Centre of Excellence with active DMD cohort), Christian Medical College Vellore (globally recognised for hematology, oncology, and rare-disease care with strong neuromuscular pediatric base), Kokilaben Dhirubhai Ambani Hospital Mumbai (advanced pediatric specialty programmes), Apollo Hospitals (Chennai flagship, Delhi, Bangalore, Hyderabad, Kolkata, with dedicated international patient services), Manipal Hospitals Bangalore, Fortis Memorial Research Institute Gurgaon, and Medanta The Medicity Gurgaon. Tata Memorial Centre Mumbai is principally an oncology institution and is not the typical anchor for DMD cases.

For families identified in tier-2 or tier-3 cities without a dedicated import pharmacy desk at the local hospital, the practical pattern is to route the case to one of the centres above, or to work through a CDSCO-licensed specialty importer in Mumbai, Delhi, or Bangalore that handles the Form 12A filing and the chain-of-custody documentation on behalf of the dispensing pediatric specialist. Reserve Meds aligns with the importer on US-side or EU-side sourcing and with the treating physician on clinical documentation. Multi-city families (the affected child in Hyderabad, the pediatric neuromuscular specialist at CMC Vellore, an adult sibling in Bangalore handling logistics, and a parent in Dubai or London paying the invoice) are common and Reserve Meds' single-coordinator model is built for that pattern.

Real cost picture for Agamree 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. Pricing in this section is expressed in USD for portability; the actual invoice converts at the prevailing rate on the day of the transaction.

Per Catalyst Pharmaceuticals' WAC filing with the North Dakota Insurance Department in February 2024, the US wholesale acquisition cost for Agamree 40 mg/mL is approximately USD 9,500 per 100 mL bottle. Because dosing is weight-based at 6 mg/kg per day, the annual drug cost varies meaningfully by patient weight. Published cost analyses estimate annual US acquisition cost in the range of USD 400,000 to USD 500,000 per patient per year for a typical pediatric DMD weight profile, with a widely cited figure of approximately USD 481,000 per year. A 20 kg ambulatory boy at 6 mg/kg per day consumes meaningfully fewer bottles per year than a 50 kg adolescent who has reached the 300 mg per day cap. The Reserve Meds quote line for the medicine is sized to the child's current weight at intake and re-estimated at the 3-to-6-month recalculation step.

International ambient-temperature shipping for Agamree is the comparatively forgiving part of the case. The product does not require refrigeration, which keeps logistics surcharges in the USD 200 to 600 per shipment range for a quarterly multi-bottle consolidation, depending on city of destination and parcel volume. The no-freeze rule constrains routing through cold cargo holds in winter on certain northern flight paths. India's Union Budget 2026-27 expanded customs-duty exemption on a set of named life-saving and rare-disease drugs, including expansion of the rare-disease list; the specific HSN code and exemption status of each Agamree shipment is 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 as a standard line item, and the unregistered status of Agamree in India makes the insurer evaluation harder. CGHS and ESIC are not structured for routine personal-import reimbursement of an unregistered pediatric orphan medicine. The NPRD 2021 INR 50 lakh ceiling is structured around one-time treatments and does not align with the indefinite chronic dosing pattern of a corticosteroid-alternative therapy; NPRD support is not the operating expectation for Agamree. Cash-pay through diaspora-funded structures is the working financial posture. Reserve Meds itemises the US-side procurement, the international logistics, and the concierge coordination fee separately on every firm quote so that any reimbursement attempt the family chooses to pursue has clean documentation to work with.

Typical timeline for Agamree in India

For a routine Indian Agamree case, 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. The ambient-temperature handling class keeps Agamree on standard international transit windows with no cold-chain time pressure. End-to-end, most families plan for two to four weeks from pediatric neuromuscular specialist decision to first dose in the child's hand. The elapsed time is dominated by upstream documentation assembly (genetic-confirmation result, weight-based dose calculation, prior corticosteroid history, monitoring plan) and downstream international logistics rather than the permit stamp.

Because Agamree is dosed once daily on an indefinite chronic basis, Reserve Meds plans repeat-shipment cadence at case acceptance rather than treating each shipment as a one-off. For families that opt to import the supply for several months in a single shipment, the per-shipment logistics surcharge can be amortised; the Form 12A filing still observes the one-hundred-average-doses-per-application cap. The weight-based dose recalculation at every 3-to-6-month pediatric checkup is the natural point to reassess bottle volume per shipment. The 3-month opened-bottle stability window aligns reasonably well with quarterly shipping cadence for many weight bands.

What your physician needs to provide

The clinical justification letter is the cornerstone of the Form 12A filing. For Agamree, the strongest letters consistently include: a pediatric neuromuscular specialist's confirmed DMD diagnosis with dystrophin gene mutation result (deletion, duplication, or point mutation) or muscle biopsy result documented; the child's current weight and weight-adjusted Agamree dose at 6 mg/kg per day, with the maximum 300 mg per day cap noted for patients at or above 50 kg; the prior corticosteroid exposure history (prednisone, deflazacort) with the documented clinical rationale for switching to vamorolone (growth stunting, bone density concerns, behavioural side effects); the proposed once-daily-with-food administration plan; and the monitoring plan covering adrenal suppression risk during illness, surgery, or stress, pediatric growth and bone health,

blood pressure, serum potassium, and the contraindication for live vaccines during therapy. The prescribing pediatric specialist's NMC registration number, the dispensing facility's drug licence, and a chain-of-custody plan from the US specialty pharmacy or EU agent to the Indian dispensing pharmacy complete the file.

The treating pediatric specialist retains the clinical decision (including the prednisone-versus-vamorolone decision, which Reserve Meds does not advise on) and the Pharmacovigilance Programme of India (PvPI) adverse-event reporting obligation through the Indian Pharmacopoeia Commission for any imported product. Reserve Meds includes the PvPI reference in the physician documentation kit; the reporting obligation itself stays with the prescribing physician.

Common questions about Agamree in India

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

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 orphan medicine as a standard line item. Reserve Meds provides the itemised documentation that lets the insurer evaluate. The claim itself is filed by the patient family or the hospital. Cash-pay is the working posture.

Will the NPRD INR 50 lakh ceiling cover Agamree?

The NPRD 2021 financial-assistance ceiling under the Rashtriya Arogya Nidhi umbrella scheme is structured around one-time treatments for rare diseases. DMD is listed as a Group 3a rare disease, and Centres of Excellence have established workflow under NPRD. The ceiling is not structured around indefinite chronic corticosteroid-alternative therapy at originator pricing, and NPRD support has not been the operating financial structure for routine Agamree cases. Families confirm eligibility with the NPRD coordinator at the designated Centre of Excellence before assuming coverage.

What is the safety profile we should be aware of?

The most common adverse events reported in the VISION-DMD pivotal trial were cushingoid features, vomiting, and vitamin D deficiency. Compared with prednisone, vamorolone showed fewer effects on linear growth, bone turnover, and behaviour. As a corticosteroid-class agent, it still carries class risks including adrenal suppression (especially during illness, surgery, or stress), immunosuppression, and the need for a tapered withdrawal on discontinuation. Live vaccines are contraindicated during therapy. The treating pediatric specialist sets the monitoring cadence and the vaccination plan.

Why Agamree rather than prednisone or deflazacort?

The clinical case is the bone, growth, and behavioural profile relative to prednisone and deflazacort. The clinical decision belongs to the treating neuromuscular specialist and the family. Reserve Meds does not advise on the comparator decision and does not endorse one corticosteroid-class agent over another. Once the prescriber has made the call, our role is procurement, logistics, and documentation.

Does the family need a specific Indian pediatric specialist registration?

Any Registered Medical Practitioner with a valid NMC registration number can support a Form 12A application. In practice, pediatric neuromuscular specialists at AIIMS, CMC Vellore, Kokilaben, Apollo, Manipal, Fortis, and Medanta have the institutional drug licence and the

pediatric neuromuscular casebook that align with how CDSCO reviewers evaluate a DMD application.

Does FCRA affect a diaspora-funded Agamree case?

The Foreign Contribution (Regulation) Act 2010 (FCRA), as proposed to be amended by the Foreign Contribution (Regulation) Amendment Bill 2026, regulates foreign donations to Indian organisations and individuals. For a patient family paying for the medicine themselves, including an adult sibling or parent overseas paying for an Indian-resident child's treatment, FCRA is generally not engaged. Where a foreign foundation or DMD-focused diaspora group is funding the treatment, FCRA registration of the recipient organisation and the donation route can become relevant. Reserve Meds does not provide FCRA legal advice; we flag the question so it reaches the right adviser early.

Where Reserve Meds fits in Agamree cases

Reserve Meds is a US-based concierge coordinator. We do not replace your pediatric neuromuscular specialist, 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 the US-side sourcing of Agamree through Catalyst Pathways' authorised specialty pharmacy network (or, where appropriate, EU-side sourcing through Santhera's local agents), ambient-temperature logistics with no-freeze handling and documented temperature logging through a bonded pharmaceutical 3PL, and the documentation kit your pediatric specialist needs for the Form 12A filing. No prior Reserve Meds case experience exists for Agamree as of this review, so standard NPP coordination applies with particular attention to weight-based dose recalculation at every pediatric checkup, the 3-month opened-bottle stability window, family training on the calibrated oral dosing syringe and the shake-before-each-dose requirement, and multilingual support where Hindi or Arabic is the family's working language. A single named coordinator carries the case from intake through the indefinite chronic dosing arc.

Next step

If an Indian child with confirmed DMD has a pediatric neuromuscular specialist considering Agamree, add the case to the waitlist. We will respond within 24 to 48 hours with a documentation kit for your specialist and an indicative cost range scaled to the child's current weight.

Reserved for you.

This guide is informational, not medical or legal advice. The named-patient framework requires a licensed Indian physician's clinical judgment; Reserve Meds is the coordinator, not the prescriber.