Agamree access in UAE: the MOHAP and EDE named-patient pathway

How families in the United Arab Emirates obtain Agamree (vamorolone) for Duchenne muscular dystrophy through the unregistered-medicine import permit administered by MOHAP and, from December 2025, the Emirates Drug Establishment.

Last reviewed 2026-05-12 by Reserve Meds clinical and regulatory team. Agamree is FDA-approved for Duchenne muscular dystrophy in patients 2 years and older; it is not registered for marketing in the UAE as of this review date. UAE families access it through the federal named-patient framework.

Quick orientation for UAE families

Agamree, the brand name for vamorolone, is an oral suspension approved by the U.S. Food and Drug Administration on October 26, 2023 for Duchenne muscular dystrophy in patients 2 years of age and older. It is a first-in-class dissociative steroidal anti-inflammatory drug, developed as a corticosteroid alternative with a more favorable bone, growth, and behavior profile than prednisone or deflazacort. Agamree is not registered in the UAE, so a family whose son needs it cannot simply fill a local prescription. The federal named-patient framework, administered through MOHAP and (from 29 December 2025) the Emirates Drug Establishment, allows a UAE-licensed physician to import a specific bottle for a specific patient under documented clinical justification. Reserve Meds coordinates the US-side sourcing and the international logistics so the case moves on a structured calendar rather than as an ad hoc effort by the family. Reserved for you.

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

Three reasons pile up to make Agamree a textbook named-patient request in the UAE. First, the drug is not on the federal register. Santhera Pharmaceuticals and its US licensee Catalyst Pharmaceuticals have not pursued UAE marketing authorisation, which is the common pattern for pediatric rare-disease products with small national patient populations. A Dubai or Abu Dhabi pharmacy cannot order Agamree through normal wholesale channels because it has no UAE registration.

Second, vamorolone's clinical positioning is specifically as a corticosteroid alternative. The VISION-DMD (VBP15-004) pivotal trial showed that switching from prednisone to vamorolone reversed growth stunting observed during prior prednisone exposure, with reduced impact on bone turnover and behavior. Families who already have a son on prednisone or deflazacort in the UAE and who are concerned about growth, bone density, or behavioral side effects often pursue the switch. The clinical case sits with the treating pediatric neurologist; the procurement is what the named-patient framework solves.

Third, the UAE pediatric DMD community is small but actively connected to international care. Many UAE families have a treating neurologist or genetic counselor abroad alongside their UAE pediatric specialist. The MOHAP and EDE framework recognizes drugs approved by reference authorities (FDA, EMA, MHRA, PMDA Japan, Health Canada) and is the legal route for delivering FDA-approved Agamree to a UAE-resident pediatric patient. The European Commission also expanded EU approval down to age 2 on a CHMP positive opinion of 27 April 2026, which strengthens the reference-authority footing.

The MOHAP and EDE named-patient pathway for Agamree

The federal pathway for a UAE-licensed physician to obtain a medicine not registered locally is the unregistered-medicine import permit. From 29 December 2025, under Federal Decree-Law No. 38 of 2024, this permit is administered through the EDE portal at ede.gov.ae, having transferred from MOHAP. The framework allows licensed hospitals and pharmaceutical establishments to import a specific medicine for a specific named patient when a reference-authority approval exists and a clinically equivalent locally registered alternative is not suitable.

For Agamree specifically, the cell-level clinical-justification angle is the corticosteroid-alternative case. A complete application typically includes:

- A clinical justification letter from the treating pediatric neurologist or neuromuscular specialist. This letter names the genetic confirmation of DMD (deletion, duplication, or point mutation by multiplex ligation-dependent probe amplification or next-generation sequencing), the patient's current corticosteroid status (treatment-naive, on prednisone, on deflazacort, or discontinued because of toxicity), and the clinical rationale for vamorolone over the standard corticosteroid options. Where the case is a switch from prednisone or deflazacort, the letter documents the specific tolerability problem driving the switch (growth stunting, bone density loss, behavioral side effects).
- The treating physician's emirate-specific medical license verification (MOHAP for the Northern Emirates, DHA for Dubai, DOH for Abu Dhabi, or Sharjah Health Authority for Sharjah).
- An anonymized patient identifier where the EDE submission permits, with age, weight, and DMD genotype attached.
- Full product detail: brand name Agamree, generic name vamorolone, 40 mg/mL oral suspension, 100 mL bottle, manufacturer Santhera Pharmaceuticals or its US licensee Catalyst Pharmaceuticals, quantity requested calculated against the weight-based 6 mg/kg per day dose, and intended treatment duration.
- The destination dispensing facility name, pharmaceutical establishment license number, and pharmacy in charge.
- A chain-of-custody plan describing the move from the US manufacturer through the importer to the dispensing pharmacy. Agamree ships ambient (20 to 25 degrees Celsius, no refrigeration, no freezing), so cold-chain logging is not required, but ambient temperature logging in transit is good practice given UAE summer heat.

Approval timelines for routine pediatric DMD cases generally fall in the 5 to 15 business days window typical for the framework. Complex first-of-molecule imports can extend to 4 to 6 weeks.

Vamorolone is a small molecule with no special handling burden, no REMS, and no controlled-substance status, which simplifies the file relative to cell therapies or scheduled drugs.

Where Agamree gets dispensed in the UAE

For pediatric DMD specifically, the institutional set that typically handles Agamree imports overlaps with established pediatric neurology and pediatric neuromuscular service lines. Sheikh Khalifa Medical City in Abu Dhabi, on the SEHA network and managed by the Cleveland Clinic, has pediatric subspecialty services and an in-house import pharmacy. Cleveland Clinic Abu Dhabi handles complex pediatric cases through its pediatric service line and pharmacy services accredited by the American Society of Health-System Pharmacists. American Hospital Dubai, a Mayo Clinic Care Network member, has pediatric oncology and pediatric subspecialty depth. King's College Hospital London Dubai has pediatric services drawing on the UK Kings College Hospital affiliation. Mediclinic City Hospital in Dubai Hea