Agamree access in Saudi Arabia

How families in the Kingdom reach Agamree (vamorolone) for Duchenne muscular dystrophy through the SFDA Personal Importation Program.

Quick orientation

Agamree is the brand name for vamorolone, a first-in-class dissociative steroidal anti-inflammatory drug for Duchenne muscular dystrophy (DMD), approved by the U.S. FDA on October 26, 2023 for patients aged 2 and older. In Saudi Arabia, vamorolone has no SFDA marketing authorization. Families who want their son on vamorolone, often switching from prednisone or deflazacort to reduce growth, bone, and behavior side effects, reach Agamree through the Saudi Food and Drug Authority's Personal Importation Program (PIP), a long-established named-patient framework administered through the treating hospital's import pharmacy or an SFDA-licensed specialty importer. Reserve Meds is the U.S.-side coordinator for that import. The neuromuscular specialist remains the prescriber. The Kingdom's pediatric centers of excellence remain the dispensing setting. Reserve Meds is the connective tissue. Reserved for you.

Why DMD families in Saudi Arabia need Agamree via NPP

Three structural reasons converge on the SFDA Personal Importation Program for Agamree. First, vamorolone is not on the SFDA national drug registration list. The product has no Saudi marketing authorization, which means it cannot be filled at any retail or hospital pharmacy through normal commercial channels regardless of how senior the prescribing neurologist is. Second, vamorolone's clinical positioning is specifically as a corticosteroid alternative with a better profile on linear growth, bone density, and behavior than prednisone or deflazacort. Families with a son already on a standard corticosteroid who are seeing growth stunting or behavioral side effects often initiate the conversation with the treating physician precisely because of this profile, and the clinical decision to switch precedes the regulatory mechanism. Third, the Kingdom's DMD population is concentrated in pediatric neurology and neuromuscular programs at KFSH&RC, KAMC, MNGHA, and a small number of private centers, where named-patient imports are routine workflow. The combination of a non-registered product, a clear clinical rationale, and concentrated tertiary care is exactly the pattern PIP was designed for.

Patients in Riyadh, Jeddah, the Eastern Province, and outside the major metro areas all flow through the same framework. The difference is operational, not regulatory: cases at tertiary centers move through the institution's import pharmacy; cases elsewhere partner with an SFDA-licensed importer in Riyadh or Jeddah.

The SFDA Personal Importation Program (PIP) for Agamree

The SFDA Personal Importation Program allows a KSA-licensed physician to request import of a specific medicine for a specific named patient when the medicine is approved by a recognized reference authority (in Agamree's case, the U.S. FDA and the European Commission) and a locally registered alternative is not clinically suitable. For vamorolone, the clinical-justification angle is the family's documented experience with prednisone or deflazacort, including growth

velocity data, bone densitometry findings where available, and behavioral notes that support the switch decision. The PIP file does not need a head-to-head clinical trial argument; it needs a clear case-specific rationale.

The application package contains a clinical justification letter from the treating neuromuscular specialist addressing the DMD diagnosis with ICD-10 code G71.01, the patient's age, weight, prior corticosteroid history with outcomes, the specific reason a locally registered corticosteroid is not suitable for this patient, and the requested dose, frequency, and treatment duration. It includes Saudi Commission for Health Specialties (SCFHS) license verification for the prescribing physician in the appropriate pediatric neurology or neuromuscular subspecialty. It includes the patient identifier in SFDA's required format. It includes product details (brand Agamree, INN vamorolone, manufacturer Santhera Pharmaceuticals with Catalyst Pharmaceuticals as U.S. license holder, country of origin, strength 40 mg/mL, presentation 100 mL bottle, requested quantity, lot, and expiry). It includes the destination dispensing facility license. And it includes the chain-of-custody plan from U.S. release through international transit to the receiving Saudi pharmacy.

For Agamree specifically, two PIP-file features deserve attention. The clinical letter should reference the VISION-DMD (VBP15-004) phase 2b trial and the FDA approval as the evidence base, and should state that vamorolone is dosed continuously rather than cyclically, which is relevant for the requested quantity calculation. The letter should also reference the corticosteroid-class tapering requirement on discontinuation, because PIP reviewers expect a treatment plan that anticipates the full course, not just initiation.

Approval timelines for routine pediatric DMD cases at established institutions typically run 10 to 21 business days. First-time filers, smaller hospitals routing through an SFDA-licensed importer, and any case where the SCFHS license is in renewal can extend to 6 to 10 weeks. SFDA's Ghad digital platform handles the regulatory transactions; the hospital's import pharmacy or the licensed importer is the operational front door.

Where Agamree gets dispensed in Saudi Arabia

For Agamree, the relevant institutions are the centers with established pediatric neurology and neuromuscular DMD programs. King Faisal Specialist Hospital and Research Centre (KFSH&RC) in Riyadh, Jeddah, and Madinah is the principal tertiary referral setting for DMD in the Kingdom, with neuromuscular specialists and in-house import pharmacy infrastructure that handles named-patient cases as routine workflow. King Abdulaziz Medical City (KAMC) and the broader Ministry of National Guard Health Affairs (MNGHA) network in Riyadh and Jeddah have established pediatric specialty services and routinely file PIP cases. King Saud University Medical City and KSAU-HS affiliated centers handle academic pediatric neurology referrals. Dr. Sulaiman Al Habib Medical Group (HMG) is the largest private network and has experienced import pharmacy operations across its multiple Riyadh, Jeddah, and Eastern Province facilities. Saudi German Health, Dr. Soliman Fakeeh Hospital in Jeddah, and Dallah Hospital in Riyadh round out the established private referral set.

Because Agamree is a room-temperature oral suspension and does not require cold-chain refrigeration, the dispensing-facility list is wider than for the typical biologic. The relevant institutional capability is pediatric neuromuscular care and PIP-experienced import pharmacy operation, not -80°C storage. Families outside the major metros typically have their PIP case routed through one of these centers or through an SFDA-licensed importer based in Riyadh or Jeddah.

Real cost picture for Agamree in Saudi Arabia

The U.S. wholesale acquisition cost (WAC) for Agamree 40 mg/mL is approximately USD 9,500 per 100 mL bottle per Catalyst Pharmaceuticals' February 2024 WAC filing with the North Dakota Insurance Department. Because dosing is weight-based at 6 mg/kg per day, the annual U.S. acquisition cost for a typical pediatric DMD weight profile runs in the USD 400,000 to USD 500,000 range, with one widely cited figure of approximately USD 481,000 per year. A typical 30-day supply ranges between one and three bottles depending on the child's weight.

For a Saudi PIP case, the cost stack has three line items. The drug cost reflects the U.S. WAC for the bottles dispensed against the named-patient case, in the order of USD 9,500 to USD 28,500 per month of supply depending on weight (approximately SAR 35,600 to SAR 106,900 at the SAR 3.75 to USD 1.00 peg). International logistics for an ambient-temperature oral product run in the USD 250 to USD 600 range per shipment (approximately SAR 940 to SAR 2,250), substantially lower than for cold-chain biologics because there is no -80°C handling, no liquid-nitrogen dry shipper, and no validated insulated packaging requirement beyond standard pharmaceutical packaging with heat-excursion logging. Reserve Meds adds a transparent coordination fee per quote, shown separately rather than embedded in the drug price.

Bupa Arabia, Tawuniya, and MedGulf Arabia handle named-patient imports case-by-case. Some plans reimburse partially against the patient's claim after delivery; many require pre-authorization with the clinical justification letter; some do not engage with non-registered medicines at all. Cas