Agamree access in Egypt: the EDA personal-importation pathway

How families in Cairo, Alexandria, and across Egypt legally obtain Agamree (vamorolone) from US or EU source supply for sons living with Duchenne muscular dystrophy when the medicine is not yet registered locally.

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Quick orientation

Agamree (vamorolone) is a first-in-class dissociative steroidal anti-inflammatory oral suspension developed by Santhera Pharmaceuticals and licensed to Catalyst Pharmaceuticals for the United States. The US Food and Drug Administration approved Agamree in October 2023 for Duchenne muscular dystrophy (DMD) in patients 2 years and older, and the European Commission followed in December 2023. In Egypt, Agamree is not yet registered as a locally marketed product through the Egyptian Drug Authority (EDA), and the families of boys living with DMD who want to switch from prednisone or deflazacort to vamorolone, or who want to start treatment on vamorolone from diagnosis, look for a structured legal route to obtain it. That route is the EDA personal-importation framework, operated under Law No. 151 of 2019, and filed through a licensed dispensing institution by the treating pediatric neurologist or neuromuscular specialist.

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Why Egyptian families need Agamree via the named-patient pathway

Egypt has one of the highest reported prevalences of consanguineous marriage in the Arab world, which contributes to a sizable national DMD population concentrated in pediatric neuromuscular clinics. Families managing DMD in Egypt have lived with prednisone and deflazacort as the corticosteroid backbone for years, often watching their sons through the growth stunting, behavioral changes, and bone-density losses that come with conventional steroid exposure across childhood. The clinical case for vamorolone sits exactly in that gap: a dissociative steroidal molecule that retains the muscle-function benefit while reducing impact on growth, bone, and behavior.

The structural reason Egyptian families reach for the EDA personal-importation pathway is simple. Agamree is not on the EDA registration list as of this module review. Families cannot fill a vamorolone prescription at a registered Egyptian pharmacy because the product has no local marketing authorisation. The two paths available are continuing on prednisone or deflazacort (locally available, well-understood, with the known toxicity profile) or pursuing named-patient import for vamorolone where the clinical case supports the switch. The decision belongs to the treating neuromuscular specialist and the family. Reserve Meds coordinates the procurement and logistics against that clinical decision.

The EDA personal-importation pathway for Agamree

The Egyptian Drug Authority was created by Law No. 151 of 2019, issued in the Official Gazette on 25 August 2019, with executive regulations issued by Prime Minister Decision No. 777 of 2020. EDA consolidates functions previously held by NODCAR, NORCB, and the Ministry of Health's Central Administration of Pharmaceutical Affairs. The personal-importation framework, sometimes described in EDA correspondence as Special Access or Compassionate Use for unregistered drugs, permits the importation of an unregistered medicine for a specific named patient where no equivalent registered product is available locally, or where the available alternative cannot meet the patient's clinical need.

A complete Agamree application typically includes:

- A clinical justification letter from the treating pediatric neurologist or neuromuscular specialist, on hospital letterhead, with original signature and stamp, stating the genetically confirmed DMD diagnosis, the current corticosteroid regimen (prednisone or deflazacort), the specific reasons vamorolone is the appropriate next step (typically growth stunting, vertebral fracture history, bone-density deterioration, behavioral or mood concerns, or a fresh DMD diagnosis where the family elects to begin on vamorolone rather than transition later)
- The treating physician's Egyptian Medical Syndicate membership number and Ministry of Health licence reference
- A recent prescription specifying brand name (Agamree), generic name (vamorolone), strength (40 mg/mL oral suspension), and quantity required (weight-based dose at 6 mg/kg daily, calculated for the planned import cycle)
- Patient identifier: copy of the national ID card or passport for the patient (or guardian for a minor)
- Full product details: manufacturer (Santhera Pharmaceuticals or Catalyst Pharmaceuticals as US label holder), country of origin, FDA or EMA approval reference, shelf life, ambient-temperature storage class
- Destination dispensing facility licence (the hospital pharmacy or licensed importer pharmacy that will physically receive and dispense the bottles)
- Chain-of-custody plan covering air freight from US or EU source through Cairo International Airport, customs clearance, and last-mile transfer to the dispensing facility under documented temperature logging with the no-freeze rule honored throughout

For Agamree, the clinical justification letter benefits from a documented genetic confirmation of DMD (dystrophin gene mutation analysis from a tertiary centre such as Kasr Al Ainy molecular medicine laboratory or an international reference lab), a clear statement of the prior corticosteroid regimen and the specific tolerability or efficacy concerns motivating the switch, a weight-based vamorolone dosing plan (6 mg/kg per day continuous, with a stated taper plan if discontinuation becomes necessary), and a monitoring plan covering adrenal suppression risk, blood pressure, growth, and vaccination status. Routine EDA personal-import authorisations for well-documented pediatric rare-disease cases are typically processed within a 3 to 6 week window once a complete package is submitted, though EDA reserves discretion at every step and complex first-import biologic-class cases can extend beyond that range.

Where Agamree gets dispensed in Egypt

Agamree is a room-temperature oral suspension, which broadens the institutional set that can handle the case relative to cold-chain biologics or cell therapies. The Egyptian institutions that routinely handle named-patient pediatric neuromuscular cases with established import pharmacy infrastructure include Cairo University Hospitals (Kasr Al Ainy), the oldest and largest academic hospital network in Egypt and the Middle East, with a Drug Information Center and dedicated pediatric neurology and rare disease services; Ain Shams University Hospitals, the second major academic hospital network in Cairo with strong pediatric and neurology programs; and Children's Cancer Hospital Egypt 57357, where the Personalized Medication Management Unit can support pharmacogenetics-adjacent rare-disease coordination.

On the private side, Dar Al Fouad Hospital in 6th of October City (Alameda Healthcare Group, JCI-accredited since 2005, with a long-standing Cleveland Clinic cooperation agreement), As-Salam International Hospital in Cairo, and the Cleopatra Hospitals Group facilities all hold pharmaceutical establishment licences capable of routing personal-import requests. For families in Alexandria, the practical pattern is to co-manage the case with a Cairo-based pediatric neuromuscular specialist while the dispensing pharmacy remains at the local hospital. Smaller regional hospitals typically route through one of the Cairo centres or through a licensed specialty importer in Cairo.

Real cost picture for Agamree in Egypt

Reserve Meds quotes patients in USD and accepts USD wire transfers. The Egyptian pound has lost more than 70 percent of its value against the US dollar since early 2022, with the USD/EGP rate near 52 to 53 in May 2026 per Trading Economics historical data, and a controlled-depreciation outlook through end of year per IMF Article IV consultation forecasts. Quoting in USD insulates the family from intra-case EGP drift between quote and