

# Cerezyme access in Egypt

How Egyptian families pursue imiglucerase enzyme replacement therapy for Gaucher disease type 1 and type 3 via the EDA named-patient pathway.

*Last reviewed 2026-05-12 by Reserve Meds clinical and regulatory team. This page combines the Egypt country research module with the Cerezyme drug module to describe the path families actually walk.*

## Quick orientation

Cerezyme (imiglucerase) is the long-established enzyme replacement therapy for Gaucher disease, manufactured by Sanofi (formerly Genzyme), approved by the US Food and Drug Administration in 1994. It is a recombinant glucocerebrosidase delivered as an intravenous infusion every two weeks, typically dosed at 60 units per kilogram body weight for symptomatic type 1 Gaucher disease, with downward titration based on clinical response and disease control. For an Egyptian family with a confirmed Gaucher diagnosis, Cerezyme is a lifelong therapy, not a course of treatment, and the access question is about year-after-year continuity, not a one-time shipment. Reserved for you.

## Why this drug is hard to source in Egypt

Cerezyme has been available in Egypt at various points through manufacturer programmes and patient-assistance arrangements, including the Gaucher Initiative supported by Sanofi in earlier years. Two patterns produce the access gap that brings Egyptian families to Reserve Meds. First, registration and stock status. Even where Cerezyme is approximately on the EDA registration list in our review, local stock availability fluctuates and patient-assistance arrangements that historically subsidised therapy do not cover every patient. The drug exists on paper; the dispensing facility does not have it on the shelf when the next infusion is due. Second, currency cost. Cerezyme is one of the most expensive lifelong therapies in the world. The US wholesale acquisition cost runs approximately USD 250,000 to 400,000 per adult patient per year, depending on dose and weight. In EGP terms, with the Egyptian pound near 52 to 53 per US dollar in May 2026 and a controlled-depreciation outlook through year-end per IMF Article IV consultation forecasts, the EGP-denominated bill has roughly tripled since early 2022. Families who self-pay or top up partial coverage face a USD-denominated commitment that local-currency budgeting cannot insulate against. Reserve Meds quotes in USD for exactly this reason.

## **The EDA named-patient pathway**

The Egyptian Drug Authority (EDA), established by Law No. 151 of 2019 and operating under the Prime Minister, permits the importation of medicines for a specific patient where the patient's clinical need cannot be met by a locally registered alternative in the required quantity. For a Gaucher patient where Cerezyme is approximately registered but stock is intermittent, the practical filing posture is Personal Importation, sometimes described in EDA correspondence as Special Access or Compassionate Use. The dispensing institution, whether a private specialty hospital pharmacy, a university hospital import desk, or a licensed Cairo-based specialty importer acting on the patient's behalf, files with EDA.

The standard application package includes a clinical justification letter from the treating physician on hospital letterhead with hospital stamp, stating the confirmed Gaucher diagnosis (enzyme assay confirming glucocerebrosidase deficiency, ideally paired with GBA gene mutation analysis), disease type and severity, baseline organomegaly, baseline platelet count and haemoglobin, prior therapy history if any, and the weight-based dose calculation; a recent prescription specifying brand name (Cerezyme), generic name (imiglucerase), strength (200 unit or 400 unit vials), quantity for the infusion cycle, and the dispensing schedule; the patient's national ID or passport copy; the treating physician's Egyptian Medical Syndicate membership number and Ministry of Health licence reference; product details including manufacturer (Sanofi), country of origin, FDA approval reference, shelf life, and storage conditions; the destination dispensing facility's pharmaceutical establishment licence; and a cold-chain plan for the 2 to 8 degree Celsius refrigerated shipment with documented temperature logging end to end.

## **Real costs in EGP and USD**

Reserve Meds quotes in USD and accepts USD wire transfers. The EGP has lost more than 70 percent of its value against the US dollar since early 2022, and many Egyptian specialty drug bills are now quoted in USD by the dispensing facility itself for the same reason. The US wholesale acquisition cost for Cerezyme runs approximately USD 250,000 to 400,000 per adult patient per year, depending on body weight and dose intensity, with the 60 unit per kilogram every-two-week regimen as the typical reference. A 50 kg patient on standard dose runs approximately USD 250,000 to 300,000 per year for the drug itself; a 90 kg patient on the same regimen runs higher.

Add international cold-chain logistics from the US source to Cairo International Airport, typically USD 400 to 1,500 per shipment depending on volume and route, with several shipments per year for an ongoing patient. Add regulatory documentation handling on the Egyptian side, varying by dispensing facility. The Reserve Meds concierge fee is itemized on every firm quote and is never bundled. We do not perform currency conversion and we do not hold local-currency accounts. The transparent USD quote means you know exactly

what to wire regardless of intra-case EGP movement. Many Egyptian families coordinate USD funds through relatives in the Gulf, the UK, or North America, which Reserve Meds supports.

## **Timing, what to expect**

Routine EDA personal-import authorisations for well-documented Gaucher cases typically process in 15 to 30 business days from submission of a complete package, recognising that Gaucher is a long-recognised rare disease with an established review track at EDA. Complex submissions, off-label dosing questions, or first-time files for a particular dispensing facility can extend to 8 to 12 weeks. Once authorisation comes through, US-side sourcing, manufacturer release, and cold-chain shipment from the US to Cairo typically run 2 to 4 weeks, with the dispensing facility handling customs clearance at Cairo airport and final delivery to the licensed infusion centre.

For an established patient already on Cerezyme who continues therapy, the practical rhythm is a continuous cycle rather than a single event. Reserve Meds frames Gaucher cases as multi-year engagements, with the documentation kit assembled once and the import workflow repeated on schedule. The EDA permit covers a defined quantity and time window, and the cycle resets on the next approval.

## **What your physician needs**

The treating physician on a Cerezyme case in Egypt is typically a haematologist, a metabolic disease specialist, or a paediatrician with rare disease expertise. The clinical justification letter for an EDA submission carries weight specific to Gaucher disease. It typically addresses the diagnostic confirmation (enzyme assay and ideally GBA gene mutation analysis), the disease classification (type 1, type 3 with neuronopathic involvement noted), the patient's clinical severity including organomegaly assessment, platelet count, haemoglobin, bone disease evaluation through DEXA or MRI where available, and growth parameters in paediatric cases. The letter addresses prior therapy outcomes if any, including substrate reduction therapy with miglustat or eliglustat where applicable, and articulates the rationale for enzyme replacement with imiglucerase specifically.

The treating physician's Egyptian Medical Syndicate membership and active Ministry of Health licence are the cornerstone. The dispensing facility, whether Cairo University Hospitals (Kasr Al Ainy), Ain Shams University Hospitals, or a private specialty hospital in the Cleopatra group, Dar Al Fouad, or As-Salam International, must hold a current pharmaceutical establishment licence and refrigerated storage. Reserve Meds supplies the physician-facing documentation kit. Filing remains with the dispensing facility.

## **UPA, Universal Health Insurance, and the private-pay context**

Egypt's Universal Health Insurance (UHI) system, launched under Law No. 2 of 2018 and operated by the Universal Health Insurance Authority (UHIA), is in mid-rollout across six geographic clusters through 2032. The pilot launched in Port Said in 2019, expanded through subsequent phases including Luxor and South Sinai, and ends with Cairo, Giza, and Qalyubia in the final phase. For named-patient Cerezyme imports in 2026, UHIA coverage is not the funding path for most patients in most governorates. Cash-pay or private insurance reimbursement is.

The Unified Procurement Authority (UPA), Egypt's centralised public-sector medicines procurement agency, handles bulk purchasing for public hospitals and the Ministry of Health. Where Cerezyme is procured through UPA channels for public-sector patients, the procurement track runs through institutional channels rather than the named-patient framework. The private-pay context applies where the patient is treated in a private specialty hospital, where the public-sector supply is intermittent and a named-patient import is the bridge, or where the patient elects private care for continuity reasons. Bupa Egypt, AXA Egypt, MetLife Egypt, Allianz Egypt, Misr Insurance, and other carriers assess Gaucher claims case by case, and pre-authorisation is the norm. We do not promise coverage from any insurer. We supply the documentation an insurer would request.

## **Pharmacovigilance and cold-chain**

Cerezyme is a recombinant biologic stored refrigerated at 2 to 8 degrees Celsius and reconstituted just before infusion. The cold-chain chain-of-custody plan in the EDA submission includes the US-side cold-pack configuration, the door-to-door temperature logger, the dedicated freight forwarder, the expected port of entry (typically Cairo International Airport), and the receiving institution's confirmation of refrigerated storage on arrival. Any temperature excursion is documented and triaged before the product enters the dispensing chain.

Egypt operates an active national pharmacovigilance system through the Egyptian Pharmacovigilance Center (EPVC), part of EDA's Central Administration for Pharmaceutical Care. The treating physician and dispensing pharmacy retain pharmacovigilance responsibility for the duration of therapy, including adverse drug reaction reporting through EPVC using Yellow Card or CIOMS forms. Anti-imiglucerase IgG antibody monitoring is part of long-term Gaucher disease management, and the treating team plans the periodic monitoring schedule. Reserve Meds does not file adverse-event reports on behalf of physicians; that obligation is tied to the local licence and stays with the treating clinician. We include the EPVC reference contacts in the physician documentation kit.

## Common questions about Cerezyme in Egypt

**Will Bupa Egypt, AXA Egypt, MetLife, or Allianz cover this?** Each insurer assesses Gaucher named-patient claims case by case. Some plans reimburse a percentage when the indication is covered even if the specific product is not on a local formulary; many require pre-authorization. We do not promise coverage from any insurer. We supply the documentation an insurer would request, and the claim filing remains with the patient or the dispensing hospital.

**Is there a substrate reduction therapy alternative?** Yes. Miglustat (Zavesca) and eliglustat (Cerdelga) are oral substrate reduction therapies and may be appropriate for selected adult type 1 Gaucher patients. The clinical choice between enzyme replacement therapy and substrate reduction rests with the treating physician based on disease severity, prior therapy response, and patient-specific factors. Reserve Meds does not steer the clinical decision.

**What about Vpriv (velaglucerase alfa) or Elelyso (taliglucerase alfa)?** Both are alternative enzyme replacement therapies for type 1 Gaucher disease. Where the treating physician determines an alternative is clinically appropriate, Reserve Meds can scope a parallel sourcing path. The EDA filing framework is the same.

**Can my paediatric patient receive Cerezyme through this pathway?** Yes. Cerezyme is FDA-approved in children, and the Egyptian paediatric centres of expertise (the paediatric units at Kasr Al Ainy and Ain Shams, Children's Cancer Hospital 57357 where Gaucher overlaps with paediatric haematology care, and the paediatric services at private specialty hospitals) handle paediatric named-patient imports routinely. The clinical justification letter typically includes weight-adjusted dosing and paediatric-specific monitoring.

**How do we handle USD payment given EGP volatility?** Reserve Meds quotes in USD and accepts USD wire transfers. Many Egyptian families coordinate USD funds through relatives in the Gulf, the UK, or North America. We do not perform currency conversion and we do not hold local-currency accounts. The transparent USD quote means you know exactly what to wire regardless of intra-case EGP movement.

## Where Reserve Meds fits

Reserve Meds is a US-based concierge coordinator. We do not replace your treating physician, the EDA, your dispensing pharmacy, or your insurance carrier. For Cerezyme specifically, our work is to align US-side sourcing, prepare the regulatory documentation kit your physician needs for the EDA filing, coordinate the international logistics to Cairo, and hold a single named coordinator through the case in both English and Arabic. Reserved for you.

## Next step

If a treating physician in Egypt is weighing Cerezyme for a patient, the waitlist is the first step. We respond within 24 to 48 hours with an eligibility confirmation and a documentation kit for the physician.

*Reserved for you.*

## Related

- [Cerezyme clinical resource](#)
- [Egypt country page](#)
- [Named-patient pathway overview](#)

## Sources

1. FDA approval and prescribing information for Cerezyme (imiglucerase), Sanofi (Genzyme).
2. Egyptian Drug Authority, personal-import framework under Law No. 151 of 2019, with executive regulations under Prime Minister Decision No. 777 of 2020.
3. Egypt Universal Health Insurance, Law No. 2 of 2018, and Universal Health Insurance Authority (UHIA) governorate phased rollout.
4. Manufacturer product monograph and US wholesale acquisition cost references for Cerezyme dosing and pricing.

**Review and oversight.** Content on this page is reviewed by the Reserve Meds clinical and regulatory team. A US-licensed pharmacist reviews every prescription before dispensing. Regulatory posture is informational, not legal advice; case-specific questions route to retained outside counsel. [Review methodology](#) ›

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