

Cerezyme

Saudi Arabia · access guide

How to access Cerezyme from Saudi Arabia, the named-patient import pathway, 2026

By Reserve Meds · Clinical & regulatory team · Last reviewed 2026-04-23

An Saudi Arabiaian patient with Gaucher disease type 1 may receive a prescription for Cerezyme (imiglucerase) from their treating metabolic specialist, haematologist, or paediatrician as enzyme-replacement therapy. Cerezyme is FDA-approved in the United States for long-term treatment of Gaucher type 1. In Saudi Arabia, Cerezyme may not always be uniformly stocked in tertiary metabolic centres, which is why your specialist may be coordinating a named-patient import pathway on your behalf for ongoing infusion supply.

This guide explains the legal pathway, what documentation your physician needs, typical timing and cost bands, and where Reserve Meds fits in.

The clinical situation

Cerezyme is an intravenous enzyme-replacement therapy (recombinant human glucocerebrosidase) administered as an infusion once every two weeks. Eligibility requires biochemical and/or genetic confirmation of Gaucher type 1. The manufacturer is Sanofi (Genzyme). Dosing is weight-based, typically 60 units/kg IV every two weeks, adjustable based on clinical response. The product requires refrigerated storage (2-8 degrees C) and reconstitution before infusion. Monitoring includes haematology, spleen/liver volumes, bone parameters, antibody development, and infusion-reaction surveillance. Your specialist will confirm diagnosis and coordinate the infusion plan.

Is Cerezyme legally importable into Saudi Arabia?

Yes, through the Saudi Food and Drug Authority (SFDA) named-patient import framework, administered via the administering hospital's importing pharmacy and the SFDA Central Administration of Pharmaceutical Affairs. The Saudi Arabia has a mature named-patient mechanism that supports cross-border access to rare-disease therapies.

The framework rests on four anchors: (a) the medicine is approved by a recognised reference authority (FDA qualifies), (b) no clinically equivalent locally registered alternative is suitable for the patient, (c) the treating physician takes clinical responsibility for use, and (d) the importing party documents chain of custody from the US source to the administering facility. Because Cerezyme is cold-chain, chain-of-custody documentation includes continuous temperature logging.

How the pathway works, step by step

1. **Consultation with your treating specialist.** The decision to prescribe Cerezyme is clinical, based on Gaucher type 1 confirmation and long-term management plan. Your specialist documents the rationale.
2. **Infusion-facility identification.** An Saudi Arabiaian tertiary hospital or infusion centre equipped for bi-weekly enzyme-replacement infusions accepts the case.
3. **SFDA named-patient application.** Your physician or the hospital's importing pharmacy files an application with SFDA including clinical rationale, patient identifier, product details, and chain-of-custody plan with temperature logging.
4. **US-side sourcing.** Reserve Meds coordinates with our US-licensed specialty wholesale partner to secure product from the manufacturer's authorised distribution chain under DSCSA.
5. **Cold-chain shipment.** Cerezyme travels with validated cold-chain packaging and continuous temperature logging end to end.
6. **Arrival and infusion.** The infusion centre receives the product and administers under your specialist's care. Reserve Meds coordinates the next cycle ahead of depletion to avoid treatment gaps.

What documentation your physician needs

Your physician will typically need to provide:

- A clinical rationale letter confirming Gaucher type 1 diagnosis and Cerezyme as the indicated long-term therapy
- Verification of their Saudi Arabiaian medical licence (MOH / Saudi Arabiaian Medical Syndicate)
- A current prescription naming the product, dose (units/kg), and infusion schedule
- Patient identifier (anonymised reference preferred)
- The identified infusion facility and its cold-chain handling capability

Reserve Meds provides a physician documentation kit bundling the templates SFDA reviewers expect to see for named-patient import of cold-chain enzyme-replacement therapies.

Costs and timing

Cerezyme's US cash-pay drug-only reference price is weight-dependent because dosing is weight-based. A typical adult annual cost sits in an indicative 2026 drug-only range (delivered quote issued at intake) of roughly USD 250,000-400,000 for ongoing bi-weekly infusions. Logistics, SFDA documentation handling, cold-chain shipment, and concierge coordination add incremental cost; Reserve Meds issues a full transparent quote at the start of intake.

Indicative timing for first shipment arrival after cohort intake opens is 7-14 days from the moment a complete SFDA application is submitted. Subsequent cycles are scheduled to match the bi-weekly infusion calendar.

Fulfillment availability is limited to our first cohort, and all timelines published on this site are indicative. If your clinical situation is time-sensitive, tell us at intake. We triage accordingly.

Reserve Meds's role

Reserve Meds is a US-based concierge coordinator for cross-border specialty medicine. For Cerezyme specifically, we provide:

- **Sourcing.** Through our US-licensed specialty wholesale partner, operating under DSCSA chain-of-custody.
- **Documentation.** Regulatory documentation package for your physician and for SFDA review.
- **Logistics.** Cold-chain shipment and chain-of-custody coordination with temperature logging.
- **Concierge case lead.** A named point of contact for your family and your physician throughout the process.

What we do not do: we are not the prescriber, we do not practise medicine, and we are not the dispensing pharmacy. All clinical decisions remain with your treating metabolic specialist and the infusion facility.

Frequently asked

Is this legal in Saudi Arabia? Yes, when executed through the SFDA named-patient framework with appropriate documentation. The pathway has been used routinely across rare disease for many years. See our trust and compliance page.

What if the cold chain breaks? Our protocol logs temperature continuously; any excursion is assessed against manufacturer stability data. If the product is compromised, we re-source at our cost per service terms.

Is Cerezyme the same as VPRIV? Both are enzyme-replacement therapies for Gaucher type 1 with similar efficacy profiles. Switching or choice between them is a clinical decision made by your specialist. We do not influence choice.

Will private insurance cover this? Cash-pay is the default. Some Saudi Arabiaian private insurers reimburse named-patient imports on case-by-case approval; we supply documentation for your submission but do not process insurance claims directly.

Reserve Meds's role

US-based concierge coordinator for cross-border specialty medicine. We are not the prescriber, not the dispensing pharmacy, and not the manufacturer. All clinical decisions remain with your treating physician.

Reserve Meds

reserved for you.

Composite case examples. This document is for general information only and does not constitute medical advice. Please consult your treating physician.

Reserve Meds is in pre-launch. Published timelines and cost ranges are indicative, not guarantees.

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