Cerdelga

Oman · access guide

How to access Cerdelga from Oman, the named-patient import pathway, 2026

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

A Oman patient with Gaucher disease type 1, a hereditary lysosomal storage disorder, may receive a prescription for Cerdelga (eliglustat) from their treating metabolic specialist or haematologist after CYP2D6 genotyping confirms eligibility. Cerdelga is FDA-approved in the United States as an oral substrate-reduction therapy, offering an alternative to intravenous enzyme-replacement therapy for eligible adults. In the Kingdom of Oman, Cerdelga may not be routinely stocked in hospital pharmacies because Gaucher disease is rare, which is why your specialist may be coordinating a named-patient import pathway on your behalf.

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

Cerdelga is an oral glucosylceramide synthase inhibitor that reduces substrate accumulation in Gaucher type 1. Eligibility requires biochemical and/or genetic confirmation of Gaucher type 1 and CYP2D6 metaboliser status (extensive, intermediate, or poor, ultra-rapid metabolisers are ineligible). The manufacturer is Sanofi (Genzyme). Dosing is determined by CYP2D6 phenotype, typically 84 mg orally twice daily for extensive/intermediate metabolisers and once daily for poor metabolisers. Monitoring includes periodic haematology, spleen/liver volumes, bone parameters, and ECG for QTc. Your specialist will confirm eligibility and the ongoing monitoring plan.

Is Cerdelga legally importable into Oman?

Yes, through the Directorate General of Pharmaceutical Affairs and Drug Control (DGPADC) named-patient import framework. The Oman has a mature named-patient mechanism that has supported cross-border access to rare-disease therapies for many years.

The DGPADC named-patient route allows a Oman-licensed physician to request import of a medicine that is not locally registered when: (a) the medicine has been approved by a recognised reference authority (FDA qualifies), (b) there is no clinically equivalent locally registered alternative, (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. Applications are reviewed by the DGPADC Drug Sector.

How the pathway works, step by step

1. **Consultation with your treating metabolic specialist.** The decision to prescribe Cerdelga is clinical, based on Gaucher type 1 confirmation and CYP2D6 result. Your specialist documents the rationale.
2. **Administering facility identification.** A Oman tertiary metabolic or haematology centre with an importing pharmacy files on behalf of the physician.
3. **DGPADC named-patient application.** Your physician or the hospital's importing pharmacy files an application with DGPADC including clinical rationale, CYP2D6 status, patient identifier, product details, and chain-of-custody plan.
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. **Temperature-controlled shipment.** Cerdelga is a stable oral capsule; shipments travel with tamper-evident packaging and end-to-end documentation.
6. **Arrival and dispensing support.** Your specialist remains the treating clinician. Reserve Meds coordinates re-supply ahead of cycle end 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, CYP2D6 phenotype, and Cerdelga as the indicated treatment
- Verification of their Oman medical licence (SCFHS / MOH)
- A current prescription naming the product, strength, and dosing schedule
- Patient identifier (anonymised reference preferred)
- The planned monitoring cadence (haematology, organomegaly, bone markers, ECG)

Reserve Meds provides a physician documentation kit bundling the templates DGPADC reviewers expect to see for rare-disease oral therapies under named-patient import.

Costs and timing

Cerdelga's US cash-pay drug-only reference price for a 30-day supply sits in an indicative 2026 drug-only range (delivered quote issued at intake) of roughly USD 26,000-30,000. Logistics, DGPADC documentation handling, 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 DGPADC application is submitted. Subsequent re-supply cycles are generally faster once the pathway is established.

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.

A brief culturally-aware note: Gaucher disease has a higher prevalence in certain regional communities, and Oman tertiary metabolic centres have meaningful Gaucher caseload. Ramadan and Hajz scheduling will be coordinated by our concierge team with your family and hospital calendar.

Reserve Meds's role

Reserve Meds is a US-based concierge coordinator for cross-border specialty medicine. For Cerdelga 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 DGPADC review, including CYP2D6 eligibility documentation.
- **Logistics.** Temperature-stable shipment and chain-of-custody coordination.
- **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.

Frequently asked

Is this legal in Oman? Yes, when executed through the DGPADC named-patient framework with appropriate documentation. See our trust and compliance page.

Why is CYP2D6 testing required? Cerdelga's dosing and eligibility depend on CYP2D6 phenotype; ultra-rapid metabolisers cannot use Cerdelga. Your specialist will order the test and interpret the result.

Can Cerdelga replace enzyme-replacement therapy? For eligible adult Gaucher type 1 patients, Cerdelga offers an oral alternative to IV ERT. Your specialist will discuss whether switching is appropriate for your case.

Will private insurance cover this? Cash-pay is the default. Some Oman 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.

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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