



Galafold in India

The CDSCO named-patient coordination pathway — indicative 2026

RARE DISEASE · FABRY DISEASE (AMENABLE VARIANTS)

The clinical situation

Galafold (migalastat) is an oral pharmacological chaperone FDA-approved for adults with Fabry disease who carry an amenable GLA variant. Manufactured by Amicus Therapeutics. Migalastat selectively binds and stabilises endogenous alpha-galactosidase A, promoting its correct trafficking to the lysosome. Dosing is 123 mg once every other day on an empty stomach. Pre-treatment workup requires GLA genotype amenability testing against the validated Amenability Table, baseline eGFR, echocardiography, and Fabry-registry enrolment per FDA labelling.

The pathway, 5 steps

- 1 Consultation & clinical rationale.** Your metabolic-genetics physician documents Fabry diagnosis, GLA genotype with amenability confirmation, organ involvement, and Galafold rationale.
- 2 Baseline workup.** Amenability test, eGFR, echocardiography, Lyso-Gb3 baseline per FDA labelling.
- 3 CDSCO named-patient application.** Physician or hospital pharmacy files clinical rationale, patient reference, amenability documentation, and chain-of-custody commitment.
- 4 US-side sourcing & logistics.** Reserve Meds coordinates product through our US-licensed DSCSA-compliant specialty wholesale partner with controlled-ambient shipment.
- 5 Arrival & first dose.** Dispensing pharmacy releases the first 30-day supply; every-other-day dosing schedule established with the treating physician.

Indicative economics

Reference US cash-pay range: USD 340,000–380,000 per year of Galafold (drug-only reference; Reserve Meds provides a transparent delivered quote at intake).

Indicative first-dose timing

7–14 days from a complete CDSCO application to first dispensation, once cohort intake opens. Indicative — not guaranteed.

Reserve Meds's role

Sourcing. US-licensed specialty wholesale partner, DSCSA chain-of-custody from Amicus authorised distribution.

Documentation. Physician kit tailored to CDSCO review, with GLA amenability and Fabry-registry enrolment annex.

Logistics. Controlled-ambient internationally tracked shipment. **Concierge case lead.** Named point of contact for family and physician through monthly refills. **We are a coordinator** — not the prescriber, not the dispensing pharmacy. All clinical decisions remain with your treating physician.

COMPOSITE EXAMPLE · PRE-LAUNCH WAITLIST

Join the Galafold × India first-cohort waitlist. *Our concierge reaches out as we open intake.*

reservemed.com/access-guides/galafold-india.html



SCAN TO JOIN

Reserve Meds · US-based concierge for cross-border specialty medicine. We are a coordinator; we are not the prescriber and not the dispensing pharmacy. All clinical decisions remain with the treating physician. Not medical advice.

Reserve Meds is in pre-launch. Service availability is limited to our first cohort; all timelines published are indicative, not guarantees. Composite case examples only.

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