Nexviazyme

Dubai · access guide

How to access Nexviazyme from Dubai, the named-patient import pathway, 2026

By Reserve Meds, Clinical and regulatory team. Last reviewed 2026-05-13.

A the UAEi patient with late-onset Pompe disease (acid alpha-glucosidase deficiency) may receive a prescription for Nexviazyme (avalglucosidase alfa-ngpt) from their treating metabolic geneticist or neuromuscular specialist. Nexviazyme is FDA-approved in the United States and manufactured by Sanofi Genzyme. It is a recombinant acid alpha-glucosidase enzyme replacement therapy administered by intravenous infusion. Local availability of Nexviazyme in Dubai can be inconsistent: the drug may not be on every specialty pharmacy's standing formulary, the specific indication may not match what is locally registered, or the strength required may be back-ordered. When that happens, a named-patient import pathway through MoPH remains a legitimate route for the patient whose physician has already prescribed the drug.

This guide explains the pathway, the documentation your physician needs, typical costs and indicative timing, and where Reserve Meds fits in.

The clinical situation

Nexviazyme is a recombinant acid alpha-glucosidase enzyme replacement therapy. Mechanism: a recombinant human acid alpha-glucosidase with increased mannose-6-phosphate residues for enhanced uptake into muscle, hydrolysing glycogen. Dosing: 20 mg/kg or 40 mg/kg by intravenous infusion every two weeks, with pre-infusion premedication considered, per FDA labeling. Baseline workup per FDA labeling includes baseline pulmonary function (FVC upright and supine), 6-minute walk test, muscle strength assessment, and cardiac evaluation. The FDA boxed warning covers hypersensitivity reactions including anaphylaxis and acute cardiorespiratory failure. Other important warnings include hypersensitivity reactions including anaphylaxis, infusion-associated reactions, and acute cardiorespiratory failure in susceptible patients. Your specialist will discuss the risk-benefit profile and schedule monitoring before initiating therapy.

Is Nexviazyme legally importable into the Dubai?

Yes, through the Dubai Ministry of Public Health (MoPH) named-patient and personal-use import framework, coordinated through a the Dubai-licensed (under DHA) treating facility's pharmacy. The Dubai has an established pathway for specialty medicines approved by reference authorities (US FDA, EMA, MHRA) but not stocked or registered for the specific indication locally.

The MoPH named-patient route allows a the UAEi-licensed physician to request import of a medicine when: (a) the medicine is approved by a recognised reference authority, (b) no clinically equivalent locally registered alternative is suitable for the patient's indication and history, (c) the treating physician takes clinical responsibility for use, and (d) chain of custody is documented from the US source to the administering facility. Applications are typically filed through the dispensing institution's import pharmacy on the physician's behalf, with approval issued on a per-patient, per-cycle quantity basis.

How the pathway works, step by step

1. **Consultation with your treating specialist.** The prescribing decision is clinical. Your specialist documents the indication, prior therapies where relevant, and rationale for Nexviazyme.
2. **Baseline screening.** Baseline pulmonary function (FVC upright and supine), 6-minute walk test, muscle strength assessment, and cardiac evaluation are confirmed and documented.
3. **MoPH named-patient application.** Your specialist or the facility's import pharmacy files the application with clinical rationale, patient reference, product strength, quantity requested, and chain-of-custody plan.
4. **US-side sourcing.** Reserve Meds coordinates with our US-licensed specialty wholesale partner to secure product from Sanofi Genzyme's authorised distribution under DSCSA chain-of-custody.
5. **Cold-chain shipment.** Nexviazyme requires refrigerated transport at 2 to 8 degrees Celsius. Shipments include temperature-monitored packaging with continuous loggers and tamper-evident seals.
6. **Arrival and first dose.** The dispensing pharmacy releases product against the physician's prescription, and your specialist initiates therapy.

What documentation your physician needs

Your physician will typically need to provide:

- A clinical rationale letter confirming diagnosis, prior therapies where relevant, and Nexviazyme as the indicated next step
- Verification of their the UAEi medical licence
- A patient identifier, anonymised reference where privacy is preferred
- Documented pre-treatment screening consistent with FDA labeling (see above)
- The planned dosing regimen (20 mg/kg or 40 mg/kg by intravenous infusion every two weeks, with pre-infusion premedication considered, per FDA labeling)
- A monitoring plan covering FVC upright/supine, 6-minute walk baselines, and pre-medication protocol

Reserve Meds provides a physician documentation kit tailored for Pompe enzyme replacement therapy therapies, including the templates MoPH reviewers commonly request.

Typical costs and indicative timing

Reserve Meds gives you a drug-only reference range plus a transparent delivered quote at intake. As an illustrative composite case, the US cash-pay reference range for a typical month of every-2-week infusions (weight-dependent) of Nexviazyme sits in an indicative 2026 band of approximately USD 50,000 to 80,000. International logistics, MoPH documentation handling, cold-chain shipping, and concierge coordination add incremental cost. The delivered quote we issue at intake shows each line separately.

Indicative timing for first dose after cohort intake opens is approximately 4 to 8 weeks from the moment a complete application is submitted, assuming the documentation package is clean on first pass. Refills ship on a rolling cadence aligned to the dosing schedule.

Service availability is limited to our first cohort. All timelines are indicative, not guarantees.

Where Reserve Meds fits in

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

- **Sourcing.** Through our US-licensed specialty wholesale partner, operating under DSCSA chain-of-custody from manufacturer to export.
- **Documentation.** Regulatory package tailored for your physician and for MoPH review, including Pompe enzyme replacement therapy class templates.
- **Cold-chain logistics.** Temperature-monitored, internationally tracked shipment to your named dispensing facility with continuous temperature loggers.
- **Concierge case lead.** A named point of contact for your family and your physician across the full case arc.

We are a coordinator. We are not the prescriber, not a pharmacy, and not a dispensing facility. All clinical decisions remain with your treating specialist, and dispensing sits with the licensed the UAEi pharmacy of record. Reserve Meds operates on cash-pay only and does not bill insurance.

Frequently asked

Is this legal in Dubai? Yes, when executed through the MoPH named-patient and personal-use framework with appropriate documentation, clinical rationale, and a licensed dispensing facility. The pathway is routinely used across oncology, rare disease, and immunology at the UAEi tertiary centers.

What about the boxed warning? The FDA boxed warning on Nexviazyme covers hypersensitivity reactions including anaphylaxis and acute cardiorespiratory failure. Your specialist performs the risk-benefit assessment, schedules monitoring, and counsels the patient per labeling. Reserve Meds does not make that clinical judgement, your physician does.

Will my private health insurance cover this? Cash-pay is the default posture. Some the UAEi private insurers reimburse named-patient imports on a case-by-case basis when the documentation package is strong. We supply documentation for your submission but do not process insurance claims.

How does cold-chain affect timing? Nexviazyme ships refrigerated. We use validated packaging with continuous temperature monitoring, and arrival temperature data is logged on every shipment.

What if my physician has not filed a named-patient request before? Named-patient import is an institutional process most major the UAEi tertiary centers (Hamad Medical Corporation, the National Center for Cancer Care and Research, and Sidra Medicine) have encountered. Our documentation kit is written for first-time applicants and tracks what MoPH reviewers commonly ask for.

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.

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