Strensiq

India · access guide

How to access Strensiq from India, the named-patient import pathway, 2026

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

An Indian patient with perinatal/infantile- and juvenile-onset hypophosphatasia (HPP) may receive a prescription for Strensiq (asfotase alfa) from their treating metabolic geneticist or paediatric endocrinologist. Strensiq is FDA-approved in the United States and manufactured by Alexion AstraZeneca Rare Disease. It is a recombinant tissue-nonspecific alkaline phosphatase enzyme replacement therapy administered by subcutaneous injection. Local availability of Strensiq in India 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 CDSCO 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

Strensiq is a recombinant tissue-nonspecific alkaline phosphatase enzyme replacement therapy. Mechanism: a bone-targeted recombinant human tissue-nonspecific alkaline phosphatase that hydrolyses inorganic pyrophosphate and restores skeletal mineralisation. Dosing: 2 mg/kg subcutaneously three times per week, or 1 mg/kg six times per week, per FDA labeling. Baseline workup per FDA labeling includes baseline alkaline phosphatase, calcium and phosphate, vitamin D, renal function, dental and skeletal imaging, and audiology. Other important warnings include injection-site reactions, hypersensitivity reactions, ectopic calcifications including ophthalmic and renal, and lipodystrophy at injection sites. Your specialist will discuss the risk-benefit profile and schedule monitoring before initiating therapy.

Is Strensiq legally importable into India?

Yes, through the Central Drugs Standard Control Organisation (CDSCO) named-patient and personal-use import framework, coordinated with the treating hospital pharmacy. India 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 CDSCO named-patient route allows an Indian-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 Strensiq.
2. **Baseline screening.** Baseline alkaline phosphatase, calcium and phosphate, vitamin D, renal function, dental and skeletal imaging, and audiology are confirmed and documented.
3. **CDSCO 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 Alexion AstraZeneca Rare Disease's authorised distribution under DSCSA chain-of-custody.
5. **Cold-chain shipment.** Strensiq 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 Strensiq as the indicated next step
- Verification of their Indian 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 (2 mg/kg subcutaneously three times per week, or 1 mg/kg six times per week, per FDA labeling)
- A monitoring plan covering ALP and pyrophosphate baselines, growth and skeletal imaging history, and the cold-chain monitoring plan

Reserve Meds provides a physician documentation kit tailored for rare disease enzyme replacement therapy therapies, including the templates CDSCO 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 therapy at maintenance dosing (weight-dependent) of Strensiq sits in an indicative 2026 band of approximately USD 35,000 to 50,000. International logistics, CDSCO 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 3 to 6 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 Strensiq 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 CDSCO review, including rare disease 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 Indian pharmacy of record. Reserve Meds operates on cash-pay only and does not bill insurance.

Frequently asked

Is this legal in India? Yes, when executed through the CDSCO 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 Indian tertiary centers.

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

How does cold-chain affect timing? Strensiq 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 Indian tertiary centers (Tata Memorial Centre, AIIMS, Apollo Hospitals, Fortis, and Max Healthcare) have encountered. Our documentation kit is written for first-time applicants and tracks what CDSCO 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.

Reserve Meds

reserved for you.

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