

## Daybue

Sri Lanka · access guide

# Daybue access in Sri Lanka: the NMRA named-patient pathway

Last reviewed 2026-05-12 by Reserve Meds clinical and regulatory team.

## Quick orientation

Patients in Sri Lanka access Daybue (trofinetide) for Rett syndrome in adult and pediatric patients aged 2 years and older through the NMRA named-patient pathway, a the National Medicines Regulatory Authority-administered mechanism that allows a Sri Lankan-licensed physician at a registered facility to import the FDA-labelled product for a specific named patient. This page details the documentation, approval timeline, and real cost in LKR.

## Why Sri Lankan patients need Daybue through the named-patient pathway

The Democratic Socialist Republic of Sri Lanka operates a structured pharmaceutical regulatory environment. Daybue (trofinetide) is regulated through NMRA (the National Medicines Regulatory Authority) channels, and a Sri Lankan family asking for Daybue is rarely asking for a medicine that does not exist locally. They are usually asking for a precise version of it that the local market has not caught up to.

Four converging patterns drive these cases. First, indication lag. Daybue's newer FDA-approved indications and dosing expansions often reach local registration 12 to 36 months after the US label. A family whose treating physician has documented a clear FDA-label fit may still find that the local label has not caught up. Second, presentation gaps. The exact strength, weight-banded dose, or pen format the prescriber needs may not be stocked at the local agent even when the medicine is registered. Third, payer denial. out-of-pocket cash with Ceylinco Healthcare, Sri Lanka Insurance Corporation, AIA Lanka, and Allianz Lanka private plans each assess specialty therapies case by case, and step-therapy or formulary rules often produce denials even when the drug is on the local register. Cash-pay families pursue cross-border supply rather than wait through appeals. Fourth, continuity of supply. When a US-stable patient relocates to Sri Lanka or visits family for an extended period, maintaining the original FDA-sourced regimen matters more than switching to a different local presentation.

In each pattern, the NMRA named-patient pathway is the mechanism that connects a Sri Lankan-licensed physician's clinical decision with US-sourced, FDA-labeled product for a specific patient. Clinically, Daybue is an oral synthetic analog of the glycine-proline-glutamate (GPE) tripeptide derived from IGF-1, administered twice daily as an oral solution, and the named-patient route preserves that mechanism rather than substituting a non-equivalent local option.

## **The NMRA named-patient pathway for Daybue**

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The pathway for a Sri Lankan-licensed physician to obtain a medicine that is not registered or not stocked locally is the Waiver of Registration (WoR) named-patient import authorisation administered by the National Medicines Regulatory Authority (NMRA) under the National Medicines Regulatory Authority Act No. 5 of 2015, which allows a treating consultant at a registered facility to apply for the import of an unregistered medicine for a specific named patient where the medicine is approved by a recognised reference authority and no clinically equivalent locally registered option is suitable. The framework allows registered healthcare facilities to import a specific medicine for a specific patient when the medicine is approved by a recognised reference authority (typically the US FDA, EMA, MHRA, PMDA Japan, or Health Canada) and a clinically equivalent locally registered alternative is not suitable. For Daybue specifically, the clinical justification typically frames the case around the precise FDA-approved indication and the documented gap in the local route.

A complete application includes a clinical justification letter from the treating physician (diagnosis, severity, prior therapies, why this specific drug, why the locally stocked option is not suitable for this case), the treating physician's Sri Lankan medical license verification through the Sri Lanka Medical Council (SLMC) and the NMRA, an anonymised patient identifier where the NMRA submission allows, full product details (brand name, generic name, manufacturer, strength, dosage form, pack size, quantity requested, intended treatment duration), the destination dispensing facility name, license number, and pharmacy in charge, and a chain-of-custody plan describing how the medicine will move from the US manufacturer through the importer to the dispensing pharmacy.

For Daybue, the clinical justification angle typically rests on one or more of three documented elements: a pediatric or weight-banded request that fits the FDA label but not the local label, a denied biologic or specialty claim where prior step-therapy has been documented, or a continuity-of-supply request for a patient previously stabilised on the US-sourced presentation. The treating physician documents the relevant clinical criteria for the prescribed indication: severity scores, biomarker levels, prior therapy failures, and the rationale for Daybue versus the next-in-line local alternative.

Approval timelines for routine cases are typically 14 to 30 business days. Complex cases (rare indication, larger quantities, first import of a given pediatric or weight-banded format) can extend to 8 to 12 weeks. NMRA retains discretion on timing, and we do not promise specific durations.

## **Where Daybue gets dispensed in Sri Lanka**

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A small group of Sri Lankan institutions handle named-patient imports as established workflow, with in-house import pharmacy infrastructure and physicians experienced with the application set. Tertiary and major private hospitals that meet this profile include Asiri Central Hospital in Colombo, Lanka Hospitals (formerly Apollo Hospitals Colombo), and Nawaloka Hospitals in Colombo. Each maintains pharmacy infrastructure appropriate to the storage requirements of the imported medicine (2 to 8 degrees Celsius cold-chain for biologics, ambient storage for oral therapies, ultra-cold or specialised handling where the FDA label requires it).

For physicians at smaller hospitals without internal import infrastructure, the common pattern is to route through a specialty importer that holds a pharmaceutical establishment license and files the NMRA application on the prescribing physician's behalf. The medicine then moves into the prescribing hospital's outpatient or specialty pharmacy under chain-of-custody documentation.

## **Real cost picture for Daybue in Sri Lanka**

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US WAC for Daybue runs in the range of USD 533,600 to USD 626,400 per year at the standard FDA-labelled regimen for Rett syndrome in adult and pediatric patients aged 2 years and older. LKR is trading at approximately 300 LKR to 1 USD, so the annual reference range converts to roughly LKR 160,080,000 to LKR 187,920,000 for the drug itself at US WAC equivalents.

International logistics for shipment to Sri Lanka typically runs USD 350 to USD 1200 depending on destination city, urgency, and presentation (cold-chain biologics carry the higher end of the range; ambient oral solids the lower). The Democratic Socialist Republic of Sri Lanka customs and NMRA permit fees are nominal relative to drug cost. Reserve Meds' concierge fee is itemised separately on every firm quote.

On the insurance side, out-of-pocket cash with Ceylinco Healthcare, Sri Lanka Insurance Corporation, AIA Lanka, and Allianz Lanka private plans each assess named-patient imports case by case. Some reimburse fully when the medicine is on their formulary even if not stocked, some reimburse a percentage subject to copay, and many require pre-authorisation. We do not promise coverage from any insurer. US manufacturer copay cards and patient assistance programs do not extend internationally; cross-border patients pay cash or rely on local payer coverage.

## **Typical timeline for Daybue in Sri Lanka**

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NMRA routine processing is typically 14 to 30 business days from a complete filing. International logistics adds 2 to 5 additional days depending on whether the presentation is ambient or cold-chain, the dispensing city, and customs clearance. End-to-end, most routine adult cases complete within 3 to 6 weeks from first complete documentation. Pediatric, weight-banded, or first-import cases can run slightly longer because presentation selection and first-import scrutiny can extend NMRA review.

For temperature-sensitive products, the dispensing facility must maintain validated storage with continuous monitoring; the manufacturer's room-temperature excursion runway on the FDA label informs how we plan the Gulf, South Asia, or North Africa shipping lane, and the cold chain is broken only at the dispensing pharmacy under documented control.

When a case is on a clinical clock (a flare, a new diagnosis with an active disease, or a treatment cycle scheduled at the dispensing centre), the practical question is which step controls the timeline. In our experience the binding step is rarely the NMRA review itself when the application is filed clean; it is usually documentation completeness on the prescriber's side or, for cold-chain biologics, the dispensing facility's storage and monitoring confirmation. The intake is where we lock the case-team contact, gather the documents in parallel, and start the US sourcing clock so that approval and product land in the same week rather than serially.

## What your physician needs to provide

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For a Sri Lankan-licensed specialist prescribing Daybue through the NMRA pathway, the clinical justification letter is the cornerstone of the application. The letter typically documents the patient's confirmed diagnosis for Rett syndrome in adult and pediatric patients aged 2 years and older, severity assessment (scoring instrument, biomarker, imaging, or biopsy as appropriate for the indication), prior therapy history including first-line options tried, and a clinical rationale for why Daybue is the appropriate next step given an oral synthetic analog of the glycine-proline-glutamate (GPE) tripeptide derived from IGF-1, administered twice daily as an oral solution.

The letter also specifies the exact dosing plan per the FDA-approved label: starting dose, maintenance dose, route of administration, schedule, and intended duration of therapy. Monitoring plan should reference any baseline laboratory or imaging requirements specific to Daybue (full blood count, liver function, infection screen, ophthalmology assessment, or pregnancy testing where the FDA label requires it), planned follow-up intervals, and dose-modification criteria for the most common adverse events.

The treating physician's Sri Lankan license number, the dispensing facility license number, and the pharmacy in charge of dispensing complete the package. For cold-chain or specialty-handling products, the dispensing pharmacy's documented storage protocol and continuous-temperature-monitoring log are part of the chain-of-custody record we share with the importer.

## Common questions about Daybue in Sri Lanka

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**Will out-of-pocket cash with Ceylinco Healthcare, Sri Lanka Insurance Corporation, AIA Lanka, and Allianz Lanka private plans cover this?** Each insurer assesses named-patient imports case by case. Some reimburse fully when Daybue is on their formulary even if not currently stocked, some reimburse a percentage subject to copay, and many require pre-authorization. We supply the documentation set that allows your insurer to assess the case; the claim itself sits with you or your hospital.

**Is the FDA-approved indication recognised by NMRA?** The NMRA named-patient pathway exists precisely to permit access when the local registration or stocking lags the FDA label. The application documents the FDA indication, the reference-authority approval, and the local gap; NMRA review focuses on the clinical justification rather than re-litigating the FDA decision.

**My physician is licensed in one emirate / state / province and the hospital is in another. Is that fine?** Any Sri Lankan-licensed physician practicing in good standing in the jurisdiction of the dispensing facility has signing authority on the clinical justification letter. The Sri Lanka Medical Council (SLMC) and the NMRA verifies the active license; the NMRA application records both the prescribing physician and the dispensing facility.

**Can I receive Daybue at home?** The dispensing facility must be Sri Lankan-licensed. The hospital outpatient or specialty pharmacy releases the medicine to you after final verification, and you then administer or self-administer at home where the FDA label permits, after the dispensing pharmacy's training. The cold-chain or controlled-storage handoff ends at the dispensing pharmacy; home storage and any handling protocol are part of your patient onboarding kit.

**What about competitors or alternative therapies in the same class?** Choice of therapy depends on the patient's full phenotype, prior therapy, and the prescriber's judgment. Reserve Meds coordinates whichever medicine the physician has prescribed; we do not substitute, advise on substitution, or promote one brand over another.

## Where Reserve Meds fits in Daybue cases

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Reserve Meds is a US-based concierge coordinator. We do not replace your treating physician, we do not replace NMRA, and we do not replace your dispensing pharmacy. For Daybue specifically, we orchestrate the US-side sourcing through a DSCSA-compliant specialty channel, build the documentation packet your physician submits, coordinate validated logistics (cold-chain with continuous temperature logging where the FDA label requires it) into Sri Lanka, and assign a single named coordinator through the case. Standard named-patient coordination under our specialty playbook applies. Presentation selection, dose-band confirmation, and patient onboarding for self-administration where applicable are the recurring operational fundamentals we expect for this drug.

Operationally, a typical Daybue case runs across four parallel tracks. The clinical track is the physician's: justification letter, dosing plan, monitoring schedule, and the next patient-facing follow-up. The regulatory track is the NMRA application packaged by the importer; we provide the documentation template, the dispensing facility license check, and the chain-of-custody attestation. The logistics track is the US-side sourcing and the validated international shipment with continuous temperature logging and customs broker coordination. The patient-experience track is the named coordinator who keeps everyone aligned on dates, addresses dispensing-pharmacy questions, and confirms the medicine has been received and stored correctly. The four tracks are run in parallel rather than in series; that is the operational difference between a 3-week and a 9-week case.

Sri Lankan tertiary specialty care concentrates at Asiri Central, Lanka Hospitals, and Nawaloka in Colombo, with the National Cancer Institute Maharagama serving as the principal oncology referral site; the NMRA Waiver of Registration pathway is the standard mechanism for unregistered specialty medicines.

### ***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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### **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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