

## Epclusa

Bahrain · access guide

# How to access Epclusa from Bahrain, the named-patient import pathway, 2026

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

A Bahraini patient with chronic hepatitis C virus (HCV) genotypes 1 through 6 in adults and paediatric patients aged 3 years and older, including those with compensated cirrhosis, and with ribavirin in those with decompensated cirrhosis may receive a prescription for Epclusa (sofosbuvir and velpatasvir) from their treating hepatologist or infectious disease physician. Epclusa is FDA-approved in the United States and manufactured by Gilead Sciences. It is a pan-genotypic direct-acting antiviral fixed-dose combination administered by oral tablet. Local availability of Epclusa in Bahrain 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 NHRA 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

Epclusa is a pan-genotypic direct-acting antiviral fixed-dose combination. Mechanism: sofosbuvir is an HCV NS5B polymerase inhibitor and velpatasvir is an HCV NS5A inhibitor; the fixed-dose combination is pan-genotypic. Dosing: one 400 mg/100 mg tablet once daily by mouth for 12 weeks, per FDA labeling; ribavirin added for decompensated cirrhosis. Baseline workup per FDA labeling includes HCV RNA quantification, genotype where available, fibrosis assessment, hepatitis B serologies (HBsAg, anti-HBc), and renal and hepatic function. The FDA boxed warning covers hepatitis B virus reactivation in HCV/HBV co-infected patients. Other important warnings include hepatitis B virus reactivation in HCV/HBV co-infected patients, symptomatic bradycardia when co-administered with amiodarone, and ribavirin teratogenicity in decompensated cases. Your specialist will discuss the risk-benefit profile and schedule monitoring before initiating therapy.

## Is Epclusa legally importable into Bahrain?

Yes, through the National Health Regulatory Authority (NHRA) named-patient and personal-use import framework, coordinated with the treating facility's pharmacy. The Bahrain 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 NHRA named-patient route allows a Bahraini-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

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1. **Consultation with your treating specialist.** The prescribing decision is clinical. Your specialist documents the indication, prior therapies where relevant, and rationale for Epclusa.
2. **Baseline screening.** HCV RNA quantification, genotype where available, fibrosis assessment, hepatitis B serologies (HBsAg, anti-HBc), and renal and hepatic function are confirmed and documented.
3. **NHRA 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 Gilead Sciences's authorised distribution under DSCSA chain-of-custody.
5. **Arrival and first dose.** The dispensing pharmacy releases product against the physician's prescription, and your specialist initiates therapy.

## What documentation your physician needs

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Your physician will typically need to provide:

- A clinical rationale letter confirming diagnosis, prior therapies where relevant, and Epclusa as the indicated next step
- Verification of their Bahraini 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 (one 400 mg/100 mg tablet once daily by mouth for 12 weeks, per FDA labeling; ribavirin added for decompensated cirrhosis)
- A monitoring plan covering HBV reactivation risk screen, fibrosis stage, and amiodarone interaction screen

Reserve Meds provides a physician documentation kit tailored for HCV direct-acting antiviral therapies, including the templates NHRA reviewers commonly request.

## Typical costs and indicative timing

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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 12-week course of Epclusa sits in an indicative 2026 band of approximately USD 18,000 to 28,000. International logistics, NHRA documentation handling, 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 2 to 5 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

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Reserve Meds is a US-based concierge coordinator for cross-border specialty medicine. For Eplusa 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 NHRA review, including HCV direct-acting antiviral class templates.
- **Logistics.** Internationally tracked shipment to your named dispensing facility with tamper-evident packaging.
- **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 Bahraini pharmacy of record. Reserve Meds operates on cash-pay only and does not bill insurance.

## Frequently asked

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**Is this legal in Bahrain?** Yes, when executed through the NHRA 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 Bahraini tertiary centers.

**What about the boxed warning?** The FDA boxed warning on Eplusa covers hepatitis B virus reactivation in HCV/HBV co-infected patients. 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. Cash-pay is the default posture in Bahrain; some employer plans cover specialty imports case-by-case. We supply documentation for your submission but do not process insurance claims.

**What if my physician has not filed a named-patient request before?** Named-patient import is an institutional process most major Bahraini tertiary centers (Shaukat Khanum Memorial Cancer Hospital, Aga Khan University Hospital, and the Indus Hospital) have encountered. Our documentation kit is written for first-time applicants and tracks what NHRA 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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### **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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