Ravicti access in Saudi Arabia through the SFDA Personal Importation Program

How Saudi families with a urea cycle disorder diagnosis source Ravicti (glycerol phenylbutyrate) for chronic lifelong management, what the PIP application package looks like, and where Reserve Meds fits.

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

Quick orientation

Ravicti is the brand name for glycerol phenylbutyrate, an oral liquid pre-prodrug used in the chronic management of urea cycle disorders (UCDs) in adults and pediatric patients aged 2 months and older who cannot be managed by dietary protein restriction or amino acid supplementation alone. It was FDA-approved on 1 February 2013 and has not historically held local commercial registration in the Kingdom of Saudi Arabia. A Saudi family with a confirmed UCD diagnosis can reach Ravicti lawfully through the Saudi Food and Drug Authority (SFDA) Personal Importation Program (PIP), with the medicine dispensed by an SFDA-licensed hospital or specialty import pharmacy on the prescription of a Saudi Commission for Health Specialties (SCFHS) licensed metabolic geneticist or pediatric specialist. Reserve Meds coordinates the US-side sourcing and the documentation kit your physician needs to file the PIP application. Reserved for you.

Why Saudi families need Ravicti through the named-patient pathway

Urea cycle disorders are ultra-rare, with a combined incidence below 1 in 35,000 live births. Manufacturer prioritisation has historically skewed to the largest reference markets, and Ravicti has not historically appeared on the SFDA-registered drug list for local commercial sale. The third of the three structural access patterns the Saudi Arabia country module describes applies most cleanly here: the drug is FDA-approved but the manufacturer has not sought SFDA registration, which is the most common pattern for ultra-rare disease therapies where the local commercial case does not justify a registration dossier. Clinically equivalent local alternatives are limited. Sodium phenylbutyrate (Buphenyl) is also rarely registered in KSA; sodium benzoate and sodium phenylacetate formulations are acute inpatient agents for hyperammonaemia and not chronic outpatient therapy; liver transplantation is a separate and very different decision.

UCDs typically present in the neonatal or early pediatric period and therapy is lifelong. A Saudi family with a confirmed UCD diagnosis must source the product continuously, year after year, for the life of the child. The chronicity amplifies the cost of any local gap. The SFDA PIP framework was designed for exactly this situation: an FDA-approved medicine, no clinically equivalent locally registered alternative, and a serious chronic condition where the treating physician documents why this specific drug is appropriate for this specific named patient. Saudi Vision 2030's Health Sector Transformation Program is expanding pediatric metabolic genetics capability and genomics diagnosis at KFSH&RC and the major tertiary centres, which surfaces more genetically confirmed UCD cases earlier and lifts demand on PIP.

The SFDA Personal Importation Program for Ravicti

The Saudi pathway for a KSA-licensed physician to obtain Ravicti is the SFDA Personal Importation Program. PIP allows a SCFHS-licensed physician to request the import of a specific medicine for a specific named patient when the medicine is approved by a recognised reference authority (here, the US FDA, supplemented by the EMA centralised marketing authorisation granted on 27 November 2015) and a clinically equivalent locally registered alternative is not suitable. Applications are filed through the dispensing institution's import pharmacy and reviewed by SFDA's Drug Sector, increasingly routed through the Ghad digital regulatory platform at ghad.sfda.gov.sa.

For Ravicti specifically, the clinical-justification angle that anchors the application is confirmatory molecular diagnosis with a documented chronic-management plan. The application is strongest when the treating physician's letter sets out (1) the molecular genetic confirmation of the specific UCD enzyme defect (OTC, CPS1, ASS1, ASL, ARG1, or NAGS deficiency) with the reporting laboratory named, (2) the current weight, plasma ammonia, glutamine, branched-chain amino acid profile, and liver function panel, (3) prior therapy history including dietary protein restriction outcomes and any prior sodium phenylbutyrate exposure and tolerability, (4) the dosing plan with the FDA-label starting estimate and titration target, and (5) the post-import pharmacovigilance commitment. SFDA reviewers are looking for the documented inability to manage on dietary protein restriction alone, which is the FDA-label gating phrase.

A complete PIP package typically includes:

- Clinical justification letter from the treating physician (diagnosis with ICD-10 coding, severity, prior therapies, why Ravicti, why a locally registered alternative is not suitable, requested dose and duration)
- Treating physician SCFHS license verification in the relevant specialty (metabolic genetics, pediatrics, or pediatric endocrinology) valid for the full requested treatment course
- Patient identifier in the SFDA-required format, linked to the national ID inside the hospital record but anonymised in the PIP file
- Product details: Ravicti 1.1 g per mL oral liquid, 25 mL multi-dose glass bottles, manufacturer Horizon Therapeutics USA, Inc. (a wholly owned subsidiary of Amgen Inc. since 6 October 2023), country of origin USA, requested quantity per refill cycle and intended treatment duration, lot and expiry
- Destination dispensing facility license showing SFDA authorisation to receive imported pharmaceuticals
- Chain-of-custody plan from the US specialty pharmacy through the freight forwarder, customs broker, and importer of record to the receiving Saudi pharmacy
- Post-import pharmacovigilance acknowledgement, with the treating physician and dispensing pharmacy committing to adverse-event reporting through the SFDA National Pharmacovigilance Center for the full course of therapy

Approval timelines for routine PIP cases run 10 to 21 business days. Because Ravicti is a recognised reference-authority drug with a well-documented FDA and EMA indication, established institutions like KFSH&RC, KAMC, MNGHA, and the major HMG facilities typically receive routine-track review. First-import cases at a smaller institution can extend to 6 to 10 weeks. Once the initial dossier is on file at a tertiary centre, subsequent refill cycles for the same named patient typically move faster.

Where Ravicti gets dispensed in Saudi Arabia

Ravicti is an oral liquid in 25 mL glass bottles, room-temperature stable (20 to 25 degrees Celsius with permitted excursions to 15 to 30 degrees Celsius), with no reconstitution and no cold chain. The capability that matters for dispensing is not infusion infrastructure but a pediatric metabolic genetics service that can prescribe, monitor, and titrate over a lifelong horizon. The Saudi institutions with this profile and with established import pharmacy workflow are:

- **King Faisal Specialist Hospital and Research Centre (KFSH&RC).** Tertiary and quaternary referral centre with operations in Riyadh, Jeddah, and Madinah. Strong rare disease, genomics, and pediatric metabolic capability with an in-house import pharmacy that handles PIP filings as routine workflow.
- **King Abdulaziz Medical City (KAMC) and the Ministry of National Guard Health Affairs network (MNGHA).** Major tertiary care with strong pediatric specialty and genomics services in Riyadh and Jeddah.
- **King Saud University Medical City (KSUMC) and KSAU-HS affiliated centres.** Academic medical centres with metabolic and rare-disease research programs and PIP filing experience.
- **Dr. Sulaiman Al Habib Medical Group (HMG).** Largest private hospital network in the Kingdom, with multiple Riyadh, Jeddah, and Eastern Province facilities, pediatric specialty depth, and routine PIP activity.

- **Saudi German Health (Saudi German Hospital).** Private multi-specialty network with named-patient experience in pediatric specialty internal medicine.
- **Dr. Soliman Fakeeh Hospital (Jeddah) and Dallah Hospital (Riyadh).** Established private referral centres that handle import-pharmacy workflow and pediatric metabolic referrals.

For families in the Eastern Province, Madinah, Tabuk, Asir, or other regions without a local pediatric metabolic specialist, the practical pattern is to be co-managed with a SCFHS-licensed metabolic geneticist at one of the Riyadh or Jeddah centres, with refills routed through that hospital's import pharmacy or through an SFDA-licensed specialty importer in Riyadh or Jeddah.

Real cost picture for Ravicti in Saudi Arabia

Ravicti pricing scales strongly with body weight and dietary protein intake. The US wholesale acquisition cost (WAC) per 25 mL bottle is approximately USD 5,200 to USD 5,300 (approximately SAR 19,500 to SAR 19,900 at the pegged rate of approximately 3.75 SAR to 1 USD). Annual cost ranges widely depending on patient size. A small pediatric patient on a low daily volume can fall at the lower end of the published WAC range of approximately USD 65,000 to USD 120,000 per year (approximately SAR 244,000 to SAR 450,000). Adolescent and adult patients at higher body weights with higher dietary protein loads sit substantially higher; published pricing observatories have reported annual list prices in the range of approximately USD 664,000 to USD 793,000 (approximately SAR 2.49M to SAR 2.97M) at adult-equivalent dosing.

International logistics for an ambient-shipped oral liquid typically runs USD 400 to USD 800 (approximately SAR 1,500 to SAR 3,000) per refill, lower than the cold-chain biologics range cited in the SFDA country module. SFDA permit and importer handling fees are itemised separately. The Reserve Meds concierge fee appears as its own line on every firm quote. US patient assistance through Horizon Cares is restricted to US insured patients and does not extend to Saudi cases; the working assumption is full WAC plus coordination cost. Bupa Arabia, Tawuniya, and MedGulf handle named-patient imports case by case, with reimbursement (where available) typically pursued after the fact through the patient's or hospital's own claim.

Typical timeline for Ravicti in Saudi Arabia

Ravicti is room-temperature stable, which removes the cold-chain handoff variables that extend timelines for refrigerated biologics. The modality-adjusted typical end-to-end timeline for a first PIP import is 6 to 10 weeks: 10 to 21 business days for routine SFDA review at an established tertiary centre (longer for first-imports at a smaller facility), 7 to 10 days for US-side specialty pharmacy procurement of the 25 mL multi-dose bottle quantity, and 3 to 5 days for ambient air freight and Saudi customs clearance. Repeat refill cycles for an established patient at the same dispensing facility typically compress to 3 to 5 weeks because the PIP dossier, the importer relationship, and the US-side procurement path are already in place. Lead-time planning at 4 to 8 weeks per refill cycle is appropriate, with periodic refill scheduling rather than one-off orders.

What your physician needs to provide

The treating physician's clinical justification letter is the cornerstone of the SFDA PIP package. For Ravicti specifically, the letter typically addresses:

- **Mechanism and FDA indication.** Glycerol phenylbutyrate is a triglyceride hydrolysed by pancreatic lipases to phenylbutyric acid, oxidised to phenylacetic acid, and conjugated with glutamine to form phenylacetylglutamine, which provides an alternative urinary nitrogen-disposal pathway. FDA-approved on 1 February 2013 for chronic UCD management; pediatric eligibility extended to patients aged 2 months and older.
- **Genetic confirmation.** Molecular confirmation of the specific UCD enzyme defect with the reporting laboratory named, and date of confirmation.

- **Prior-line documentation.** Dietary protein restriction history and its inability to maintain plasma ammonia targets; prior sodium phenylbutyrate exposure and tolerability if applicable; why a locally registered alternative is not suitable.
- **Dosing plan.** Either FDA-label milligram-to-milligram conversion from prior sodium phenylbutyrate, or a starting estimate of 4.5 to 11.2 mL per square metre of body surface area per day divided across three daily doses with meals (maximum total daily dose 17.5 mL), or 0.6 mL per gram of dietary protein per 24 hours.
- **Monitoring plan.** Plasma ammonia targets (below half the upper limit of normal for patients aged 6 and older; morning ammonia below the age-appropriate upper limit of normal for younger children where fasting samples are not practical), plasma glutamine, branched-chain amino acids, phenylacetic acid to phenylacetylglutamine ratio where relevant, liver function tests, and growth and nutritional monitoring in pediatric patients.
- **Pharmacovigilance commitment.** Written acknowledgement that adverse-event reporting through the SFDA National Pharmacovigilance Center will be maintained for the full course of therapy.
- **Physician license.** Verification of active SCFHS registration in the relevant specialty, with renewal date confirmed for the requested treatment window.

Pediatric dietitian co-signature on the dietary protein prescription is good practice, given that Ravicti is approved as an adjunct to dietary protein restriction, not a replacement.

Common questions about Ravicti in Saudi Arabia

Will Bupa Arabia, Tawuniya, or MedGulf cover this?

Each insurer assesses named-patient imports case by case. Some plans reimburse fully when the medicine appears on the insurer's formulary, even when the local hospital pharmacy did not have it stocked. Others reimburse a percentage. Many require pre-authorisation with the clinical justification letter attached. We supply the documentation set that lets your insurer assess; the claim sits with you or your hospital. Cash-pay is the default operating posture, with reimbursement sought after delivery if your plan permits.

Will my Ministry of Health-employed metabolic geneticist's letter be sufficient?

Yes. SCFHS-licensed physicians at Ministry of Health hospitals, KFSH&RC, KAMC, MNGHA, and other public-sector institutions have full signing authority on PIP applications. The clinical justification letter is the cornerstone of the package. Private-sector physicians at HMG, Saudi German, Fakeeh, Dallah, and similar institutions also have signing authority under their institutional license.

What is the safety profile?

The FDA label lists the most common adverse reactions in adults as diarrhoea, flatulence, and headache, and in pediatric patients as upper respiratory tract infection, vomiting, diarrhoea, decreased appetite, fatigue, and rash. The principal warning is neurotoxicity from elevated plasma phenylacetic acid; clinical monitoring for somnolence, confusion, and lethargy when PAA is elevated is part of standard care.

What ammonia monitoring frequency does SFDA expect?

SFDA does not prescribe a fixed monitoring schedule, but the post-import pharmacovigilance commitment means the treating physician documents an ammonia and metabolite monitoring plan that aligns with FDA-label guidance. Plasma ammonia, glutamine, branched-chain amino acids, and liver function tests are followed routinely, with frequency individualised to age, dose, and clinical trajectory.

Why Ravicti rather than sodium phenylbutyrate?

The metabolic genetics literature reports better palatability and lower sodium intake with Ravicti, which can be material in young children and in patients with cardiac or fluid considerations. The choice is the prescribing physician's. Reserve Meds does not endorse one product over the other.

How are lifelong refills handled given the chronic nature of UCD?

Refills run on a periodic schedule, typically every 4 to 8 weeks depending on pack quantity and projected daily volume. The first PIP dossier seeds the file; subsequent refill permits typically clear faster once the operational rails are in place. Reserve Meds tracks the refill calendar and pre-stages the next cycle's documentation so the family is not chasing the timeline.

Where Reserve Meds fits in Ravicti cases

Reserve Meds is a US-based concierge coordinator. We do not replace your physician, SFDA, or your dispensing pharmacy. For Ravicti specifically, we orchestrate the US-side sourcing through a DSCSA-compliant specialty pharmacy that holds the 25 mL bottle inventory, prepare the documentation kit your Saudi physician needs to file the PIP application (with the molecular confirmation, dosing plan, monitoring plan, and SFDA pharmacovigilance acknowledgement templates pre-built for UCD cases), align the ambient air-freight shipment plan with the Saudi importer, and assign a single named coordinator who carries the family through the first cycle and the recurring lifelong refill cadence. Ravicti is one of the recurring ultra-rare named-patient inquiries we expect through our Gulf intake channel. No prior Reserve Meds closed-case experience for Ravicti as of this page date; standard NPP coordination applies.

Next step

If you have a confirmed UCD diagnosis and your Saudi physician has identified Ravicti as the right chronic-management step, add your case to our waitlist. We will confirm eligibility within 24 to 48 hours and send the documentation kit to your physician.

Reserved for you.

This guide is informational, not medical or legal advice. The SFDA Personal Importation Program requires a SCFHS-licensed physician's clinical judgment; Reserve Meds is the coordinator, not the prescriber.

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