Ravicti access in UAE through the MOHAP and EDE named-patient pathway

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

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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 is FDA-approved (1 February 2013) and currently not registered with the UAE drug authority for local commercial sale. A UAE family with a confirmed UCD diagnosis can reach Ravicti lawfully through the unregistered-medicine import permit, historically administered by MOHAP and, since 29 December 2025, administered through the Emirates Drug Establishment (EDE) portal. The medicine is dispensed by a UAE-licensed hospital or specialty import pharmacy on the prescription of the treating metabolic geneticist or pediatric specialist. Reserve Meds coordinates the US-side sourcing and the documentation kit your physician needs to file the EDE permit. Reserved for you.

Why UAE 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 is not on the UAE federal drug register for local commercial sale. Two of the three structural access gaps the UAE country module describes apply here together: the drug is not registered in the UAE at all, and clinically equivalent local alternatives are limited. Sodium phenylbutyrate (Buphenyl) is also rarely registered in the UAE; 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 UAE 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 MOHAP and now EDE unregistered-medicine import permit 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 patient. The Emirati Genome Programme and growing local pediatric metabolic capability mean more UAE families are receiving genetically confirmed UCD diagnoses earlier, which lifts demand on the pathway.

The MOHAP and EDE named-patient pathway for Ravicti

The federal pathway for a UAE-licensed physician to obtain Ravicti is the unregistered-medicine import permit. Since 29 December 2025, applications are filed through the EDE portal at ede.gov.ae rather than directly with MOHAP. The framework allows hospitals and licensed pharmaceutical establishments to import a specific medicine for a specific patient where the medicine is approved by a recognised reference authority and a clinically equivalent locally registered alternative is not suitable. Ravicti meets the reference-authority criterion through its FDA approval and its EMA centralised marketing authorisation granted on 27 November 2015.

For Ravicti specifically, the clinical-justification angle that anchors the application is confirmatory molecular diagnosis. 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), (2) the current weight and a current plasma ammonia and metabolite panel, (3) prior therapy history including dietary protein restriction outcomes and any prior sodium phenylbutyrate exposure and tolerability, (4) the dosing plan with starting estimate and titration target, and (5) the monitoring plan. The EDE reviewers

are looking for the documented inability to manage on dietary protein restriction alone, which is the FDA-label gating phrase.

A complete package typically includes:

- Clinical justification letter from the treating physician (diagnosis with genetic confirmation, severity, prior therapies, why Ravicti, why a locally registered alternative is not suitable)
- Treating physician's UAE medical license verification (MOHAP, DHA, DOH, or Sharjah Health Authority, depending on practice location)
- Patient identifier (anonymised reference where the EDE submission allows)
- 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), quantity requested per refill cycle and intended treatment duration
- Destination dispensing facility name, license number, and pharmacy in charge
- Chain-of-custody plan from the US specialty pharmacy through the importer to the UAE dispensing pharmacy

Approval timelines for routine UCD cases are typically 5 to 15 business days, consistent with the country-wide range. First-import cases for a molecule the EDE has not previously cleared can extend to 4 to 6 weeks. Because Ravicti has a long international named-patient track record across the GCC, repeat refill cycles for the same patient typically run at the faster end of the range once the initial dossier is on file.

Where Ravicti gets dispensed in the UAE

Ravicti is an oral liquid in 25 mL glass bottles, room-temperature stable, 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. The UAE institutions with this profile and with established import pharmacy workflow are:

- **Sheikh Khalifa Medical City (SKMC), Abu Dhabi**