

[Skip to main content](#)

[Home](#) / [Drugs](#) / [Idhifa](#) / [In UAE](#)

Idhifa access in the UAE: the MOHAP and EDE named-patient pathway

How patients in the United Arab Emirates access Idhifa (enasidenib) for IDH2-mutated relapsed or refractory acute myeloid leukemia when the medicine is not locally registered.

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

1. Quick orientation

Idhifa is the brand name for enasidenib, an oral once-daily small-molecule inhibitor of mutant isocitrate dehydrogenase-2 (IDH2). The US Food and Drug Administration approved it on 1 August 2017 for adults with relapsed or refractory acute myeloid leukemia (AML) carrying a confirmed IDH2 mutation. In the United Arab Emirates, Idhifa is not locally registered. UAE patients with biopsy-confirmed IDH2-mutated relapsed or refractory AML reach the medicine through the federal unregistered-medicine import permit administered by the Ministry of Health and Prevention (MOHAP) and, from 29 December 2025, through the Emirates Drug Establishment (EDE) portal at ede.gov.ae. The pathway exists because IDH2-mutated AML is biomarker-defined, the FDA-approved alternative class (IDH1 inhibitors) is not interchangeable, and the global ex-US patient population is too small for routine UAE registration. Reserved for you.

2. Why UAE patients need Idhifa via the named-patient pathway

The United Arab Emirates operates one of the most developed pharmaceutical regulatory environments in the Gulf, but three structural access gaps repeat in oncology. A drug can be on the federal register and still not stocked at a particular hospital. A drug can be registered for a different indication than the one the treating hematologist is prescribing for. Or, in the case of Idhifa, the drug can be FDA-approved but not registered in the UAE at all, because the addressable patient population in the country in any given year is in the dozens rather than the hundreds.

Idhifa is the textbook third pattern. Servier holds the ex-US commercial rights after acquiring Agios's oncology business in 2020. The European Medicines Agency application was withdrawn by Celgene in early 2020 and has not been refiled centrally as of the most recent public disclosures. UAE registration has not followed. For a UAE hematologist treating a patient whose pathology has returned IDH2-mutated relapsed or refractory AML, no domestic stock exists to dispense.

The clinical case for the unregistered-medicine pathway is unusually clean for Idhifa. Idhifa is the only FDA-approved IDH2-selective inhibitor; ivosidenib targets IDH1 and is not interchangeable; venetoclax-based regimens and hypomethylating agents work through different mechanisms in different clinical settings. Once the IDH2 mutation is confirmed on a CLIA-certified panel or the Abbott RealTime IDH2 Assay companion diagnostic, substitution to a locally registered alternative is not a clinical option. That fact carries the medical-necessity narrative for the EDE filing.

3. The MOHAP and EDE named-patient pathway for Idhifa

The federal pathway for a UAE-licensed physician to obtain an unregistered medicine for a specific patient is the unregistered-medicine import permit. The framework has historically been administered by MOHAP and, under Federal Decree-Law No. 38 of 2024, it is now administered through the EDE portal as of 29 December 2025. Compassionate-use provisions in the UAE legal framework define compassionate use as the use of a medical product for a patient with a serious illness or life-threatening condition outside of clinical trials when no alternative treatment options are available. IDH2-mutated relapsed or refractory AML is the case the framework is built for.

A complete application typically includes:

- A clinical justification letter from the treating hematologist (diagnosis, severity, prior therapies, why Idhifa, why a locally registered alternative is not suitable)
- The treating physician's UAE medical license verification (MOHAP, DHA, DOH, or Sharjah Health Authority, depending on practice location)
- An anonymised patient identifier where the EDE submission allows
- Full product details: Idhifa, enasidenib, Bristol Myers Squibb, 100 mg tablets, bottle of 30, quantity sufficient for the planned treatment cycle
- The destination dispensing facility name, license number, and pharmacy in charge
- A chain-of-custody plan from US specialty distributor through the importer to the dispensing hospital pharmacy

The clinical-justification angle that matters most for Idhifa is biomarker confirmation. The treating hematologist documents the IDH2 mutation on the pathology report (Abbott RealTime IDH2 Assay or an equivalent CLIA-certified next-generation sequencing panel), states the relapse or refractory status against prior therapy (induction regimen, hypomethylating agent or venetoclax-based combination, allogeneic stem cell transplant where applicable), and explicitly notes that no IDH2-selective inhibitor is registered in the UAE and that an IDH1 inhibitor is not substitutable for IDH2-mutated disease. This biomarker-driven framing is precisely what the unregistered-medicine pathway is designed to accommodate.

Approval timelines for routine cases are typically 5 to 15 business days. Complex cases (rare drug, novel mechanism, off-label use, larger quantities, first import of a given molecule) can extend to 4 to 6 weeks. Idhifa is a first-of-class molecule with limited prior UAE filing history, so the case can fall in the upper portion of that range, particularly for the first import of the molecule into a given dispensing facility. Urgent oncology cases can sometimes receive expedited review, although timelines remain at the authority's discretion and are not promised.

4. Where Idhifa gets dispensed in the UAE

Idhifa is an oral oncology product. It does not require infusion infrastructure, cold-chain storage, or cell-therapy capability. The dispensing requirement is a UAE-licensed hospital outpatient pharmacy or specialised import pharmacy with an established workflow for unregistered-medicine imports, paired with a UAE-licensed hematologist supervising the case.

UAE institutions that handle named-patient hematology imports as established workflow include Cleveland Clinic Abu Dhabi (M42 group, Al Maryah Island, with adult oncology and pharmacy services accredited by the American Society of Health-System Pharmacists), Sheikh Khalifa Medical City (SKMC, SEHA network, JCI-accredited, with oncology and hematology services), Tawam Hospital in Al Ain (SEHA network, national referral center for oncology developed in collaboration with the Johns Hopkins Sidney Kimmel Comprehensive Cancer Center, with established hematology and palliative care), American Hospital Dubai (Mayo Clinic Care Network member, with oncology and hematology), King's College Hospital London Dubai, Mediclinic City Hospital in Dubai Healthcare City, and the larger NMC Healthcare flagship sites.

For physicians at smaller hospitals without import infrastructure, the common pattern is to route through a Dubai- or Abu Dhabi-based specialty importer that holds a pharmaceutical establishment license and files the EDE application on the prescribing physician's behalf.

5. Real cost picture for Idhifa in the UAE

The UAE dirham is pegged to the US dollar at approximately 3.67 AED to 1 USD, so US-denominated costs translate predictably into AED. Three line items frame the case economics.

First, drug cost. The Bristol Myers Squibb US wholesale acquisition cost for Idhifa is approximately USD 36,034 per 30-day supply at the 100 mg once-daily dose, which corresponds to roughly AED 132,000 per month. A 12-month course at full label dose runs to approximately USD 420,000 to USD 440,000 (AED 1.54M to AED 1.61M) before any rebates, copay assistance, or 340B pricing, which are US-only programmes that do not extend to international patients. Drugs.com price-guide data shows 30 tablets of 50 mg branded Idhifa at roughly USD 35,000, consistent with the BMS-published figure.

Second, international logistics. Idhifa is a small-molecule oral tablet, room-temperature stable at 20 to 25 degrees Celsius with permitted excursions between 15 and 30 degrees Celsius. International logistics for an ambient shipment to the UAE typically runs USD 400 to USD 1,500 (approximately AED 1,500 to AED 5,500) depending on destination emirate and urgency window. No gel packs, no temperature loggers, no cold-chain quarantine risk.

Third, regulatory and coordination. UAE customs and EDE permit fees are nominal relative to the drug cost. Regulatory documentation handling fees and Reserve Meds' concierge fee are itemised separately on every firm quote. On the insurance side, Daman National Health Insurance (operator of the government-funded Thiqa programme for UAE nationals in Abu Dhabi), GIG Gulf, Sukoon Insurance, ADNIC, and Orient Insurance each assess named-patient imports case by case. Cash-pay is the default posture, with patients pursuing reimbursement after the fact where their plan covers.

6. Typical timeline for Idhifa in the UAE

The EDE timeline for routine unregistered-medicine permits is typically 5 to 15 business days. Idhifa is an ambient small-molecule product, which removes the cold-chain transit window from the timeline. End-to-end, a typical Idhifa case in the UAE runs as follows: 24 to 48 hours from intake to eligibility confirmation by Reserve Meds; 3 to 7 days for the treating hematologist and the dispensing hospital pharmacy or specialty importer to assemble the application and IDH2 biomarker documentation; 5 to 15 business days for EDE review (longer for first import of the molecule into a given facility); 3 to 5 days for US sourcing, release documentation, and ambient courier shipment; 1 to 2 days for UAE customs clearance under the permit; and final verification and dispense at the hospital pharmacy. A six-month minimum trial of Idhifa is recommended in the FDA label because the differentiation mechanism produces delayed responses, with median time to first response of approximately 1.9 months and median time to best response of approximately 3.7 months, so the supply cadence is planned for repeat shipments from the first case.

7. What your physician needs to provide

The clinical justification letter is the cornerstone of the EDE application for Idhifa. The treating UAE hematologist documents the patient's diagnosis as relapsed or refractory acute myeloid leukemia; states the IDH2 mutation status with explicit reference to the testing platform (Abbott RealTime IDH2 Assay or an equivalent CLIA-certified IDH2 next-generation sequencing panel) and the date of the pathology report; itemises prior lines of therapy with response and relapse documentation; states the reason a locally registered alternative is not suitable (the only FDA-approved IDH2-selective inhibitor is Idhifa; IDH1 inhibitors are not interchangeable for IDH2-mutated disease; venetoclax-based regimens, hypomethylating agents, and intensive chemotherapy work through different mechanisms and are options in different clinical settings); states the planned dosing regimen as 100 mg orally once daily continuous, taken at approximately the same time every day, with or without food, until disease progression or unacceptable toxicity, with a minimum six-month trial per the FDA label given the differentiation mechanism; describes the monitoring plan, including vigilance for differentiation syndrome at every visit (the boxed warning), complete blood count and chemistries including bilirubin at baseline and at least monthly, QT interval monitoring where concomitant medication considerations apply, and management of leukocytosis with hydroxyurea without dose interruption when needed.

The letter is co-filed with the physician's UAE license verification, the dispensing facility license number, the requested pack and quantity (Idhifa 100 mg tablets, bottle of 30, typically a 30-day supply per bottle), and the chain-of-custody plan describing how the medicine will move from the US specialty distributor through the importer to the hospital pharmacy.

8. Common questions about Idhifa in the UAE

Will Daman, Thiqa, GIG Gulf, Sukoon, ADNIC, or Orient cover the cost? Each insurer assesses named-patient imports case by case. Some reimburse in full when the medicine is on their formulary even if not stocked, some reimburse a percentage subject to copay, and several require pre-authorisation. Thiqa, the government-funded programme for UAE nationals administered by Daman, has the broadest specialty coverage in Abu Dhabi. We do not promise coverage from any insurer. We supply the documentation set that allows your insurer to assess the case; the claim itself sits with you or your hospital.

Will my DHA-licensed or DOH-licensed hematologist's letter be sufficient? Yes. Any UAE-licensed physician practicing in good standing in the emirate of the dispensing facility has signing authority on the clinical justification letter, provided the license matches the emirate of the dispensing facility. If the facility is in Dubai, a DHA-licensed hematologist is the natural fit; if the facility is in Abu Dhabi, a DOH-licensed hematologist.

Is the IDH2 mutation test available in the UAE? Yes. Major UAE oncology pathology services run IDH2 mutation testing on CLIA-equivalent next-generation sequencing panels. Where a UAE patient has had testing at a US, UK, or other reference laboratory, that pathology report is accepted in the EDE filing.

What is the safety profile I should know about? Idhifa carries a boxed warning for differentiation syndrome, which can be fatal if not recognised and treated. Symptoms include fever, dyspnea, hypoxia, pulmonary infiltrates, pleural or pericardial effusion, rapid weight gain, peripheral oedema, and renal dysfunction. The boxed warning is managed through prescriber education and the label rather than through a restricted-distribution REMS programme.

Is there a competitor or alternative we should consider first? For IDH2-mutated relapsed or refractory AML, enasidenib is the only FDA-approved IDH2-selective inhibitor. Ivosidenib (Tibsovo) targets IDH1 and is not interchangeable. Venetoclax-based regimens, hypomethylating agents, and intensive chemotherapy are different mechanisms used in different clinical settings. Selection between Idhifa and other options is made by the treating hematologist; Reserve Meds does not endorse one regimen over another.

Is Idhifa a controlled substance? No. Idhifa is not on the US DEA schedule and is not a controlled substance under UAE law. Federal Narcotics Department coordination does not apply. The standard EDE unregistered-medicine permit is the operative framework.

9. Where Reserve Meds fits in Idhifa cases

Reserve Meds is a US-based concierge coordinator. We do not replace your treating hematologist, the EDE, the dispensing hospital pharmacy, or your insurer. What we do for an Idhifa case is verify eligibility within 24 to 48 hours; supply your physician's team with a documentation kit referencing the BMS prescribing information and the IDH2 biomarker requirements; align the US-side sourcing through DSCSA-compliant US specialty distributors with the UAE importer; coordinate the ambient courier shipment under chain-of-custody documentation; and provide a single named coordinator across the case. The Reserve Meds operating model maps cleanly onto Idhifa: room-temperature handling, no infusion or reconstitution, biomarker-confirmed eligibility that simplifies the medical-necessity narrative for the EDE filing, and a clearly absent local registration story. No prior Reserve Meds case experience predates this page; standard NPP coordination applies.

10. Next step

If your UAE hematologist has confirmed IDH2-mutated relapsed or refractory AML and recommends Idhifa, start the request and we will reach out within 24 to 48 hours.

Reserved for you.

Review & oversight. Content on this page is reviewed by Reserve Meds's clinical and regulatory team. A US-licensed pharmacist reviews every prescription before dispensing. Regulatory posture is informational, not legal advice; case-specific questions route to retained outside counsel. Review methodology >

Last medically reviewed: 2026-05-12.