Idhifa access in Egypt: the EDA personal-import named-patient pathway

How patients in Egypt access Idhifa (enasidenib) for IDH2-mutated relapsed or refractory acute myeloid leukemia when the medicine is not registered locally, with attention to the boxed warning on differentiation syndrome.

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

1. Quick orientation

Idhifa is the brand name for enasidenib, an orally bioavailable small-molecule selective inhibitor of mutant isocitrate dehydrogenase-2 (IDH2). The US Food and Drug Administration granted regular approval to Idhifa on 1 August 2017 for adult patients with relapsed or refractory acute myeloid leukemia (AML) carrying an IDH2 mutation, as detected by an FDA-approved companion diagnostic. The approval was issued together with the Abbott RealTime IDH2 Assay as the companion diagnostic. In Egypt, Idhifa is not registered with the Egyptian Drug Authority (EDA). The European Medicines Agency application was withdrawn in early 2020, leaving most ex-US patients reaching the medicine through their national personal-import frameworks. Patients in Egypt access Idhifa through EDA Personal Importation under Law No. 151 of 2019, filed by a dispensing institution on behalf of a named patient. Reserved for you.

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

Egypt operates one of the largest pharmaceutical markets on the African continent and one of the most active named-patient import workflows in the Arab world. The structural gap between FDA-approved oncology and what is registered with EDA is widest for low-volume biomarker-driven assets, and Idhifa sits in the third category EDA filings most commonly address: not registered locally at all. The marketing authorisation application was never filed in Egypt by either Celgene (prior holder, acquired by Bristol Myers Squibb in November 2019) or Servier (which acquired ex-US rights to enasidenib in May 2020). There is no EDA registration record for Idhifa, no Egyptian importer carrying it as a routine stock item, and therefore no domestic pharmacy from which the drug can be dispensed without a personal-import authorisation.

The indication is also biomarker-driven. Patients reach Idhifa only after IDH2 mutation testing confirms eligibility, which means the prescribing haematologist already knows the patient cannot use an IDH1 inhibitor, a BCL-2 inhibitor, or a hypomethylating agent in place of enasidenib. Substitution is not a clinical option once the IDH2 mutation is identified. The cumulative Egyptian patient population is small because IDH2 mutations occur in roughly 8 to 19 percent of AML cases depending on cohort, and only a subset are in the relapsed or refractory setting. The economics structurally favour the personal-import route. Egypt's adult haematology programmes at Kasr Al Ainy and Ain Shams send IDH2 mutation testing to in-house or partner molecular laboratories, and patients with confirmed IDH2 mutation who have relapsed after intensive chemotherapy, hypomethylating agent therapy, or allogeneic transplant are the typical Idhifa case profile.

3. The EDA named-patient pathway for Idhifa

The Egyptian Drug Authority was created by Law No. 151 of 2019, issued 25 August 2019 in the Official Gazette No. 34 bis (A), with executive regulations under Prime Minister Decision No. 777 of 2020 on 29 March 2020. EDA is a public service authority affiliated to the Prime Minister and consolidates functions previously held by the National Organization for Drug Control and Research (NODCAR), the National Organization for Research and Control of Biopharmaceuticals (NORCB), and the Ministry of Health's Central Administration of Pharmaceutical Affairs (CAPA). EDA permits the importation of unregistered medicines for a specific patient under defined conditions, most importantly where no equivalent

registered product is available locally. This is the pathway commonly referred to as Personal Importation, sometimes described in EDA correspondence as Special Access or Compassionate Use for unregistered drugs.

The standard application package for Idhifa includes the clinical justification letter from the treating haematologist, on hospital letterhead, original and stamped, stating the AML diagnosis, the confirmed IDH2 mutation status (citing the Abbott RealTime IDH2 Assay result or an equivalent CLIA-certified IDH2 next-generation sequencing panel report), the relapsed or refractory status with prior lines of therapy documented, and the specific reason this product is required rather than a locally available alternative; a recent prescription specifying brand name (Idhifa), generic name (enasidenib), strength (50 mg or 100 mg tablets), dosage form, and quantity required for the planned coordination window; a patient identifier (copy of the national ID card or passport); the treating physician's Egyptian Medical Syndicate (EMS) membership number and Ministry of Health licence reference; product details (Bristol Myers Squibb as US marketing authorisation holder, country of origin, FDA approval reference, room-temperature storage condition); the destination dispensing facility licence; and a chain-of-custody plan describing the route from the US specialty distribution channel through to the licensed dispensing pharmacy in Egypt.

The clinical-justification angle that matters most for Idhifa is the documentation of IDH2 mutation status and prior-line failure. The treating haematologist references the Stein et al. AG221-C-001 study (Blood, 2017) for the underlying response data (19 percent complete remission for a median 8.2 months; an additional 4 percent complete remission with partial haematologic recovery for a median 9.6 months; 34 percent of baseline transfusion-dependent patients becoming transfusion-independent), and frames the case as the only mechanism-matched FDA-approved option for the patient's IDH2-mutated relapsed or refractory disease. Routine EDA personal-import authorisations for well-documented oncology cases are typically processed in a 3 to 6 week window once a complete package is submitted, though this varies meaningfully by case complexity. EDA reserves discretion at every step. Reserve Meds does not promise EDA timelines and is not the filer.

4. Where Idhifa gets dispensed in Egypt

Idhifa is a small-molecule oral tablet supplied in 50 mg and 100 mg strengths in bottles of 30 tablets. It is room-temperature stable, with storage at 20 to 25 degrees Celsius and permitted excursions between 15 and 30 degrees Celsius. No refrigeration is required, no reconstitution is required, and the tablets are swallowed whole with or without food. The dispensing requirement in Egypt is an EDA-licensed hospital outpatient pharmacy or licensed specialty importer, paired with a treating haematologist whose EMS registration and Ministry of Health licence support the personal-import filing.

Egyptian adult haematology programmes with established named-patient import workflow include Cairo University Hospitals (Kasr Al Ainy), the oldest and largest academic hospital network in Egypt and the Middle East, with a Drug Information Center, a dedicated adult haematology and oncology unit, and an institutional import workflow; Ain Shams University Hospitals, the second major academic hospital network in Cairo with strong oncology and haematology services; Dar Al Fouad Hospital in 6th of October City, Giza, a JCI-accredited private super-specialty hospital with over 250 bone marrow transplants, the Cleveland Clinic cooperation agreement from 1999, and active adult haematology services; As-Salam International Hospital in Cairo; and the Cleopatra Hospitals Group, the largest private hospital group in Egypt with oncology infrastructure across multiple Cairo facilities. Children's Cancer Hospital Egypt 57357 is the leading pediatric oncology centre but Idhifa is not approved for paediatric patients, so adult AML cases route through the adult-haematology centres above. Smaller hospitals outside Cairo, Giza, and Alexandria typically route Idhifa cases through one of these centres or through a Cairo-based licensed specialty importer.

5. Real cost picture for Idhifa in Egypt

Reserve Meds quotes Idhifa cases in USD and accepts USD wire transfers. The Egyptian pound has lost more than 70 percent of its value against the US dollar since early 2022, with the USD/EGP rate near 52 to 53 in May 2026 per IMF Article IV consultation forecasts. Quoting in USD insulates the case from intra-case currency drift. Three line items frame the economics.

First, drug cost. The manufacturer-published US wholesale acquisition cost for Idhifa on the BMS pricing information site is approximately USD 36,034 per 30-day supply at either the 50 mg or 100 mg once-daily dose, with Drugs.com price-guide data showing 30 tablets of 50 mg branded Idhifa at roughly USD 35,000. At full label dose, a 12-month course corresponds to approximately USD 420,000 to USD 440,000 at US WAC before any rebates or assistance, none of which is portable to Egyptian patients given BMS Access Support is US-only. At the May 2026 exchange rate this corresponds to roughly EGP 1.87 million per 30-day fill and approximately EGP 22 to EGP 23 million per year.

Second, international logistics. Idhifa is the most permissive class of cold-chain handling. The product ships in standard ambient packaging with no temperature monitoring, no insulated shipper, no gel packs, and no excursion-limited transit window. International logistics from the US source to Cairo International Airport typically runs USD 400 to USD 1,500 (approximately EGP 21,000 to EGP 80,000) depending on volume and route.

Third, Egyptian regulatory documentation handling fees on the dispensing facility side, which vary by hospital and importer, and the Reserve Meds concierge fee, itemised on the firm quote and never bundled. On the insurance side, Bupa Egypt, AXA Egypt, MetLife Egypt, Allianz Egypt, Misr Insurance, MedGulf Egypt, Orient Takaful, and Royal Insurance each assess named-patient imports case by case. The Universal Health Insurance Authority (UHIA) coverage is still rolling out by governorate phase under Law No. 2 of 2018 and does not currently cover most specialty imports for most patients. Cash-pay is the dominant posture. Many Egyptian families coordinate USD funds via relatives in the Gulf, the UK, or North America.

6. Typical timeline for Idhifa in Egypt

Idhifa is an ambient oral product, which removes the cold-chain transit window. End-to-end, a typical Idhifa case in Egypt runs as follows: 24 to 48 hours from intake to eligibility confirmation by Reserve Meds; 5 to 10 days for the treating haematologist's team to assemble the personal-import application with the IDH2 mutation report, the prior-line clinical narrative, and the dispensing facility documentation; 3 to 6 weeks for routine EDA review on a well-documented oncology case, with complex cases extending to 8 to 14 weeks where supplementary documentation is requested mid-review; 3 to 5 days for US sourcing through the BMS specialty distribution channel, release documentation, and ambient courier shipment to Cairo International Airport; 1 to 2 days for customs clearance under the EDA authorisation; and final verification and dispense at the hospital outpatient pharmacy. Because Idhifa is dosed continuously at 100 mg once daily until progression or unacceptable toxicity, and the label specifies a minimum six-month trial before declaring lack of response given the differentiation mechanism, Reserve Meds plans repeat-shipment cadence from the first case rather than treating each fill as a one-off.

7. What your physician needs to provide

The clinical justification letter is the cornerstone of the EDA personal-import application for Idhifa. The treating Egyptian haematologist documents the diagnosis (relapsed or refractory AML), the confirmed IDH2 mutation status (citing the specific assay used and the variant identified), the prior lines of therapy attempted and failed (intensive chemotherapy, hypomethylating agents, allogeneic stem cell transplant where applicable), and the specific clinical reason enasidenib is required rather than a locally available alternative, with the substitution argument framed against the IDH2-selective mechanism (ivosidenib targets IDH1 and is not interchangeable; venetoclax-based regimens, hypomethylating agents, and intensive chemotherapy are different mechanisms used in different clinical settings). The letter states the planned dosing regimen as 100 mg orally once daily, continuous, with or without food, no loading dose, with treatment continued until disease progression or unacceptable toxicity, citing the FDA-approved label minimum six-month trial before declaring lack of response.

The monitoring plan addresses the boxed warning for differentiation syndrome, which can be fatal if not recognised and treated. The letter documents that the patient and family have been counselled on warning signs (fever, dyspnea, hypoxia, pulmonary infiltrates, pleural or pericardial effusion, rapid weight gain, peripheral oedema, renal dysfunction); that vigilance will be highest in the first three months; that corticosteroids and haemodynamic monitoring are initiated and dose interruption is considered for confirmed differentiation syndrome; that complete blood count and chemistries including

bilirubin will be obtained at baseline and at least monthly, with dose reduction to 50 mg once daily permitted for Grade 3 or 4 hyperbilirubinemia not attributable to differentiation syndrome; that QT interval monitoring is appropriate given concomitant medication considerations; and that leukocytosis without differentiation syndrome will be managed with hydroxyurea. The letter is co-filed with the physician's EMS membership and Ministry of Health licence reference, the dispensing facility licence, the requested pack and quantity (Idhifa 100 mg tablets, bottle of 30, packs sufficient for the planned coordination window), and the chain-of-custody plan from the US BMS specialty distribution channel through to the dispensing pharmacy in Egypt. Pharmacovigilance reporting through the Egyptian Pharmacovigilance Center (EPVC) using Yellow Card or CIOMS forms applies for the duration of therapy and is the prescribing physician's obligation.

8. Common questions about Idhifa in Egypt

Will Bupa Egypt, AXA Egypt, MetLife, or Allianz cover the cost? Each insurer assesses named-patient imports case by case. Some plans reimburse a percentage when the drug treats a covered indication even if the specific product is not on a local formulary; many require pre-authorisation. We supply the documentation an insurer needs to assess. The claim filing remains with the patient or the hospital. Cash-pay is the default posture, and many Egyptian families reimburse themselves later if coverage applies.

Does UHIA cover specialty imports like Idhifa? Not as a general rule. The Universal Health Insurance rollout under Law No. 2 of 2018 began in Port Said in 2019 and is phased through to 2032, with Cairo, Giza, and Qalyubia in the final phase. For most named-patient specialty imports in 2026, UHIA coverage is not the funding path.

How do we handle USD payment given EGP volatility? Reserve Meds quotes in USD and accepts USD wire transfers. Many Egyptian families coordinate USD funds via relatives in the UAE, Saudi Arabia, Kuwait, Qatar, the UK, or the US. We do not perform currency conversion and we do not hold local-currency accounts. The transparent USD quote means you know exactly what to wire regardless of intra-case EGP movement.

What is the differentiation syndrome boxed warning and how is it managed? 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 label calls for monitoring at every visit with vigilance highest in the first three months, and prompt initiation of corticosteroids and haemodynamic monitoring on confirmed cases. The treating haematologist owns this monitoring. Reserve Meds supplies the documentation kit; clinical management stays with the treating clinician.

Is there a competitor or alternative 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. The treating haematologist makes the regimen call; Reserve Meds does not.

Is Idhifa a controlled substance? No. Idhifa is not a DEA Schedule I through V drug and is not subject to controlled-substance import controls in Egypt. The standard EDA Personal Importation framework under Law No. 151 of 2019 applies.

9. Where Reserve Meds fits in Idhifa cases

Reserve Meds is a US-based concierge coordinator. We do not replace your treating haematologist, EDA, your dispensing pharmacy, or your insurer, and we do not act as an importer of record in Egypt. What we do for an Idhifa case is verify eligibility within 24 to 48 hours; supply your haematologist's team with a documentation kit referencing the BMS prescribing information, the August 2017 FDA approval and AG221-C-001 trial data, the IDH2 mutation confirmation requirement, and the EDA Personal Importation application format; align the US-side sourcing through the BMS specialty distribution channel with the Egyptian dispensing facility; coordinate the ambient courier shipment under chain-of-custody documentation to Cairo International Airport; and provide a single named coordinator across the case, in Arabic on the patient side and English on the family side where the family is split across the diaspora. No prior Reserve Meds case experience predates this page; standard NPP coordination applies. Idhifa is a strong fit for the Reserve Meds operating

model given the ambient-tablet logistics, the biomarker-confirmed eligibility that simplifies the medical-necessity narrative, and the clearly absent local registration story.

10. Next step

If your Egyptian haematologist has confirmed IDH2-mutated relapsed or refractory acute myeloid leukemia 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 ›
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