Rezdiffra access in Egypt

EDA Personal Importation for adults with MASH (NASH) and F2 to F3 fibrosis. Non-invasive diagnostic gate. Coordinated end to end.

Quick orientation

Rezdiffra (resmetirom) is the first FDA-approved therapy for adults with noncirrhotic metabolic dysfunction-associated steatohepatitis (MASH, previously called NASH) with moderate to advanced liver fibrosis at stages F2 to F3. It is an oral once-daily small molecule developed by Madrigal Pharmaceuticals and received accelerated FDA approval on 14 March 2024. The Egyptian Drug Authority (EDA) has not registered Rezdiffra for the Egyptian market as of May 2026, which means Egyptian hepatologists who identify a patient eligible for the FDA label reach for the drug through the EDA Personal Importation pathway under Law No. 151 of 2019. Egypt carries one of the highest regional prevalences of NAFLD and MASH, driven by elevated rates of type 2 diabetes, central obesity, and metabolic syndrome, so the inbound case pattern from hepatologists in Cairo, Giza, and Alexandria is already steady. Reserve Meds runs the orchestration on the US side and walks alongside your physician on the Egypt side. Reserved for you.

Why patients in Egypt need Rezdiffra via the named-patient pathway

MASH affects an estimated 1.5 to 6.5 percent of adults in the wider MENA region, with Egyptian-specific estimates trending toward the higher end of that range given the prevalence of metabolic syndrome and the long-running burden of viral and metabolic liver disease in the country. The treatment gap before Rezdiffra was real: hepatologists managed lifestyle, glycaemic control, and supportive care, but had no FDA-approved disease-modifying option specific to the MASH histologic indication. The FDA approval in March 2024 created a step-change in regional demand, and Egyptian hepatology referral patterns have moved quickly.

Inside Egypt, Rezdiffra fits squarely in the country module's "not registered locally at all" access pattern. Even with the European Commission conditional marketing authorisation granted on 19 August 2025, country-by-country EU launch sequencing has been gradual, and Egypt is not within the EU rollout. EDA does not list Rezdiffra. The local-importer shelf is empty. There is no equivalent registered product that addresses the same MASH F2-F3 indication. Where the patient and the treating hepatologist align on the FDA-supported indication, and the local market cannot fill the prescription, the EDA Personal Importation pathway is the practical, lawful route.

The EDA Personal Importation pathway for Rezdiffra

The Egyptian Drug Authority was created by Law No. 151 of 2019, issued in the Official Gazette on 25 August 2019, with executive regulations under Prime Minister Decision No. 777 of 2020. EDA permits the importation of unregistered medicines for a specific patient where no equivalent registered product is available locally. The pathway is commonly referred to as Personal Importation, and the application is filed through the dispensing institution's import pharmacy at a major academic centre, a JCI-accredited private hospital, or a Cairo-based licensed specialty importer.

For Rezdiffra, the clinical justification angle is the non-invasive diagnostic gate (NIT). The FDA label does not require liver biopsy. Diagnosis of MASH with F2 or F3 fibrosis can be supported by non-invasive testing such as transient elastography (FibroScan) with kPa values in the F2 to F3 range, magnetic resonance elastography (MRE), or validated blood-based panels such as the Enhanced Liver Fibrosis (ELF) test, often combined with FAST or MAST composite scores. EDA reviewers expect to see the specific NIT result documented in the file. A FibroScan report with the kPa value and the associated fibrosis stage interpretation, signed by the performing physician, is the most common form of evidence in Egyptian cases, since FibroScan is widely available at tertiary hepatology centres in Cairo and Alexandria.

The standard application package includes the clinical justification letter on hospital letterhead, the prescription specifying Rezdiffra brand name, generic name (resmetirom), strength, and quantity, a copy of the patient's national ID or passport, the treating physician's EMS membership and Ministry of Health licence reference, the NIT report (FibroScan, MRE, or ELF), the baseline liver biochemistry panel (ALT, AST, alkaline phosphatase, total bilirubin), the destination dispensing facility's licence, and a chain-of-custody plan. Rezdiffra is room-temperature stable (20 to 25 degrees Celsius with permitted excursions to 15 to 30) and does not require cold-chain logistics. Routine EDA Personal Importation authorisations are typically processed in a 3 to 6 week window once a complete package is filed, varying by case complexity. EDA reserves discretion at every step. Reserve Meds does not file with EDA and is not an importer of record in Egypt.

Where Rezdiffra gets dispensed in Egypt

The institutions equipped to run a routine Rezdiffra import workflow are the hepatology-strong tertiary centres in Cairo, Giza, and Alexandria. Cairo University Hospitals (Kasr Al Ainy) operates one of the largest hepatology services in the Middle East, with a Drug Information Center and an institutional import workflow. Ain Shams University Hospitals carry strong hepatology services and routine experience with imported specialty medicines. Dar Al Fouad Hospital in 6th of October City is JCI-accredited and part of the Alameda Healthcare Group, with established import pharmacy capacity and an active hepatology referral base. As-Salam International Hospital and the Cleopatra Hospitals Group also handle named-patient cases as routine practice across their Cairo facilities. FibroScan availability at all of the centres above means the baseline NIT measurement and the longitudinal monitoring measurements can be co-located with the import pathway. For patients whose hepatologist is at a regional hospital, co-management with one of the Cairo centres or routing through a licensed specialty importer is the practical path.

Real cost picture for Rezdiffra in Egypt

Reserve Meds quotes patients in USD and accepts USD wire transfers. With the USD/EGP rate near 52 to 53 in May 2026 and a controlled-depreciation outlook through end of year, quoting in USD insulates the patient from intra-case currency drift. Three line items shape the firm quote:

- **Drug acquisition cost.** US wholesale acquisition cost for Rezdiffra is approximately USD 47,400 per year as published by Madrigal at launch, with state price transparency filings in January 2025 reflecting a per-bottle WAC of approximately USD 4,115.90 for a 30-tablet bottle (one month of therapy at the once-daily dose). At twelve refills before any discount, the annual total approaches USD 49,000.
- **International ambient logistics, US to Cairo.** Because Rezdiffra is a room-temperature oral tablet shipped under ambient conditions, the logistics surcharge sits at the lower end of the Egypt corridor range, typically USD 400 to USD 1,000 per shipment routed through Cairo International Airport.
- **Reserve Meds concierge fee.** Itemised on the firm quote, never bundled into the drug cost.

Insurer behaviour for named-patient imports varies by carrier. Bupa Egypt, AXA Egypt, MetLife Egypt, Allianz Egypt, Misr Insurance, and other carriers operating in Egypt assess named-patient claims case by case. Some plans reimburse a portion when the drug treats a covered indication even if the specific product is not on a local formulary. Pre-authorisation is typically required. Cash-pay remains the dominant posture for named-patient hepatology cases in Egypt, and many patients reimburse themselves later if coverage applies. UHIA does not currently cover most specialty imports in most governorates under the still-phased Universal Health Insurance rollout.

Typical timeline for Rezdiffra in Egypt

Routine EDA Personal Importation authorisations for well-documented hepatology cases with FibroScan-confirmed F2 or F3 fibrosis sit inside the 3 to 6 week typical window once a complete package is filed. Because Rezdiffra is room-temperature stable and ships ambient, the post-authorisation logistics leg is shorter than the comparable leg for a refrigerated biologic. End to end, a first Rezdiffra shipment to a Cairo or Alexandria dispensing pharmacy is typically achievable within a 5 to 9 week window from intake to in-hand at the hospital pharmacy for cases with complete

documentation. Refill cadence runs at monthly intervals (one 30-tablet bottle per month), and Reserve Meds plans quarterly or semi-annual shipment rhythms with the destination physician based on monitoring visit alignment. Timelines vary case by case and EDA reserves discretion.

What your physician needs to provide

Your treating hepatologist, with EMS membership and an active Ministry of Health licence, prepares the clinical justification letter on hospital letterhead. The letter sets out the MASH diagnosis with F2 to F3 fibrosis stage, the supporting NIT result (FibroScan kPa value, MRE elastography result, or ELF score), the prior management trajectory including lifestyle and glycaemic optimisation, the metabolic comorbidity profile (type 2 diabetes, obesity, dyslipidaemia, hypertension where present), and the rationale for Rezdiffra rather than an off-label alternative.

The prescription specifies brand name (Rezdiffra), generic name (resmetirom), strength (80 mg or 100 mg depending on body weight band: 80 mg once daily for body weight less than 100 kg, 100 mg once daily for body weight greater than or equal to 100 kg), the 30-tablet bottle format, and the dispensed quantity sufficient for a defined refill cycle. The letter includes the monitoring plan per the FDA label, covering baseline and periodic ALT, AST, alkaline phosphatase, and total bilirubin, with defined thresholds for dose interruption. Concomitant medication review is documented, especially statins and CYP2C8 substrates or inhibitors. The Egyptian Pharmacovigilance Center (EPVC) reporting framework runs through the full course of therapy, and the documentation kit includes EPVC reference contacts.

Common questions about Rezdiffra in Egypt

Do I need a liver biopsy to start Rezdiffra? No. The FDA-approved label does not require liver biopsy for diagnosis or treatment initiation. Non-invasive testing such as FibroScan, MRE, or ELF (often combined with FAST or MAST composite scores) is the practical gate. EDA reviewers expect to see the specific NIT result in the file. Your hepatologist makes the diagnosis call.

Will Bupa Egypt, AXA Egypt, MetLife, or Allianz cover this? 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, and many require pre-authorisation. Reserve Meds supplies the documentation an insurer needs to assess. Claim filing remains with the patient or hospital.

Does UHIA cover Rezdiffra? Not as a general rule, and not consistently across governorates yet. The UHI rollout is phased through to 2032. For most named-patient specialty imports in 2026, UHIA coverage is not the funding path; cash-pay or private insurance reimbursement is.

Can I receive Rezdiffra at home, or do I need to pick it up at a hospital? The dispensing facility must hold a valid Egyptian pharmacy or hospital licence. For an oral tablet like Rezdiffra, a hospital outpatient pharmacy or specialty importer pharmacy dispenses the bottle to the patient, who then takes the daily dose at home. Administration is once daily with or without food.

What about side effects? The most commonly reported adverse events in the MAESTRO-NASH trial were diarrhoea and nausea, both more frequent on resmetirom than placebo and generally early in therapy. The FDA label includes warnings around drug-induced liver injury, hepatic decompensation in unrecognised cirrhosis, and gallbladder-related adverse reactions. Your hepatologist owns the safety assessment.

How long will I be on this drug? Therapy is chronic and ongoing per the FDA label, taken alongside diet and exercise. There is no defined stop date. Continuation is based on your hepatologist's longitudinal assessment.

Where Reserve Meds fits in Rezdiffra cases

Reserve Meds is a US-based concierge coordinator. We do not replace your hepatologist, we do not replace EDA, we do not replace the licensed dispensing pharmacy, and we do not act as an importer of record in Egypt. For a Rezdiffra case the orchestration is concrete. We confirm eligibility within 24 to 48 hours, we send a documentation kit to the treating physician

with Arabic-language patient-facing summaries where the family requests them, we source through a DSCSA-compliant US specialty pharmacy channel while EDA reviews, we coordinate the ambient-temperature international shipment to Cairo International Airport, and we run a single named coordinator throughout the case. The monthly refill cadence shapes the cadence of our relationship with the patient: this is not a single-order interaction, it is a longitudinal care-coordination relationship.

Next step

If you have a confirmed MASH diagnosis with F2 or F3 fibrosis on FibroScan, MRE, or ELF, and your hepatologist has indicated Rezdiffra is the right next step, the practical move is to start the intake. We confirm eligibility within 24 to 48 hours and send the documentation kit to your physician.

Reserved for you.

About Rezdiffra

Hepatology (MASH F2-F3)
Manufacturer: Madrigal Pharmaceuticals
Modality: Oral tablet, room temperature
Full drug page

About Egypt

EDA Personal Importation, Law 151/2019
Cairo gateway, USD quote
Egypt country page

Related

Rezdiffra in Saudi Arabia
Rezdiffra in the UAE
Rezdiffra in India
Personal Importation pathway
MASH condition page