Repatha access in Egypt: the EDA named-patient pathway

How families and patients in Egypt obtain Repatha (evolocumab) for familial hypercholesterolemia and atherosclerotic cardiovascular disease through the Egyptian Drug Authority personal importation framework.

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

Quick orientation

Repatha is the Amgen brand name for evolocumab, a fully human monoclonal antibody that blocks PCSK9 and raises hepatic LDL-receptor density, increasing clearance of LDL cholesterol from the bloodstream. The US FDA first approved Repatha in August 2015 for adults with heterozygous and homozygous familial hypercholesterolemia and adults with clinical atherosclerotic cardiovascular disease, expanded it in December 2017 for cardiovascular risk reduction based on the FOURIER trial, and in September 2021 added a pediatric heterozygous FH indication for patients aged 10 and older while lowering the pediatric HoFH threshold to 10 years. Egypt's familial hypercholesterolemia detection has improved meaningfully over the last decade, driven in part by the cardiac programmes at the Magdi Yacoub Heart Foundation and other tertiary cardiology centres, but PCSK9-inhibitor stocking in Egypt is concentrated and uneven. The EDA personal importation pathway is the route for FH families and post-MI patients who need continuity of supply at a workable price.

Reserved for you.

Why patients in Egypt reach for Repatha through NPP

Repatha is registered in Egypt and approved in more than 60 countries globally, so the Egyptian NPP case is typically not about non-registration. It is about three structural gaps. First, stocking depth. PCSK9 inhibitors are concentrated in tertiary cardiology and lipid-clinic settings in Cairo, Giza, and Alexandria, and a patient in a tier-2 city in the Delta, Upper Egypt, or Sinai can be many hours from any pharmacy that actually carries Repatha. Second, the FH cohort itself. Familial hypercholesterolemia patients, particularly pediatric HeFH and HoFH patients aged 10 and older, often have LDL-C levels that are unresponsive to statin and ezetimibe alone. For these families, the choice is not Repatha versus an alternative; it is Repatha or untreated cardiovascular risk in a child or adolescent. Egypt's FH detection has improved via Magdi Yacoub Heart Foundation cardiac programmes and through cascade-screening initiatives at tertiary centres, so families now arrive at the question of continuous PCSK9 therapy with a confirmed diagnosis but uncertain local supply.

Third, secondary prevention after myocardial infarction. Patients who have already had a cardiovascular event and are at very high risk of a second event sometimes prefer the documented FOURIER trial regimen on a validated supply chain. The cash-pay international patient profile that Reserve Meds serves aligns to this use case. Pricing also matters in Egypt specifically. Amgen reduced US WAC by 60 percent in October 2018, from approximately USD

14,100 per year to USD 5,850 per year, and launched the AmgenNow direct-to-patient program in 2025 at approximately USD 239 per month for US patients. For a biologic monoclonal antibody Repatha sits at the accessible end of the price spectrum, and that matters meaningfully in a market where the EGP has lost more than 70 percent of its value against the dollar since early 2022.

The EDA personal importation pathway for Repatha

EDA was created by Law No. 151 of 2019, issued in the Official Gazette on 25 August 2019, with executive regulations issued by Prime Minister Decision No. 777 of 2020 on 29 March 2020. EDA is a public service authority affiliated with the Prime Minister, consolidating functions previously held by NODCAR, NORCB, and the Ministry of Health's Central Administration of Pharmaceutical Affairs. The EDA Drug Registration Sector handles registration files, and the Egyptian Pharmacovigilance Center (EPVC) handles post-market safety.

EDA permits the importation of unregistered or stocked-but-unavailable medicines for a specific patient when an equivalent registered product cannot meet the clinical need. This is the pathway commonly described as Personal Importation, with Special Access and Compassionate Use appearing as variations in EDA correspondence. The application is filed through the dispensing institution's import pharmacy, typically a private specialty hospital, a university hospital import desk, or a licensed Cairo-based specialty importer.

For Repatha the clinical justification angle is lipid- and indication-specific. A complete application typically includes:

- A clinical justification letter on hospital letterhead from the treating cardiologist, lipidologist, or pediatric cardiologist (for FH patients aged 10 to 17), documenting the FDA-approved on-label indication: adult HeFH, adult HoFH, adult ASCVD requiring additional LDL-C lowering, established CV disease requiring CV risk reduction, pediatric HeFH from age 10, or pediatric HoFH from age 10
- Lipid-panel results documenting LDL-C trajectory on maximally tolerated statin therapy with or without ezetimibe; for FH cases, genetic testing or clinical-diagnostic criteria documentation (Dutch Lipid Clinic Network or Simon Broome criteria); for ASCVD secondary-prevention cases, documentation of the qualifying event
- A recent prescription specifying brand name (Repatha), generic name (evolocumab), presentation (140 mg SureClick autoinjector, 140 mg prefilled syringe, or 420 mg Pushtronex on-body infusor), and quantity for the dosing schedule chosen
- A patient identifier (national ID card or passport) plus Egyptian Medical Syndicate membership number and Ministry of Health licence reference for the treating physician
- Product details: manufacturer Amgen Inc. (Thousand Oaks, California), country of origin (United States), FDA approval reference, shelf life, storage conditions (refrigerated 2 to 8 degrees Celsius; 30-day room-temperature stability after removal)
- The destination dispensing facility licence and a cold-chain plan including data-logger inclusion

Routine EDA personal-import authorisations for well-documented cardiology and lipidology cases typically run in a 3 to 6 week window once a complete package is submitted. Pediatric FH cases

often involve additional documentation review for weight-and-age verification and may extend slightly. Reserve Meds does not promise EDA timelines and is not the filer.

Where Repatha gets dispensed in Egypt

Repatha is a refrigerated biologic that the patient or caregiver self-administers by subcutaneous injection after physician or nurse training. The natural homes for Repatha dispensing in Egypt are the tertiary cardiology centres and the major academic hospital lipid clinics. The Magdi Yacoub Heart Foundation is the leading cardiovascular surgical and pediatric cardiology centre in Egypt, with FH detection programmes and import experience for advanced cardiology therapies. As-Salam International Hospital in Cairo is one of the most advanced cardiac centres in Egypt, the first hospital in the Middle East to earn JCI Clinical Care Certification for Acute Myocardial Infarction, which is directly relevant to the post-MI secondary-prevention cohort. Cairo University Hospitals (Kasr Al Ainy) and Ain Shams University Hospitals operate cardiology services with lipid clinics and routine PCSK9 dispensing capability. Dar Al Fouad Hospital (Alameda Healthcare Group, JCI-accredited) and the Cleopatra Hospitals Group facilities round out the private-sector network.

For pediatric FH patients aged 10 and older, the pediatric cardiology service at Magdi Yacoub Heart Foundation and the pediatric units at Kasr Al Ainy and Ain Shams are the natural homes. Smaller clinics outside Cairo, Giza, and Alexandria typically route Repatha cases through a Cairo-based licensed specialty importer that files the EDA permit and delivers under chain-of-custody to the prescribing cardiologist's outpatient pharmacy. The 30-day room-temperature stability window for unopened cartons provides usable slack on transit and last-mile delivery within the country.

Real cost picture for Repatha in Egypt

Reserve Meds quotes Egyptian patients in US dollars and accepts USD wire transfers. The EGP has lost more than 70 percent of its value against the dollar since early 2022, with the USD/EGP rate near 52 to 53 in May 2026. Quoting in USD insulates the patient from intra-case currency drift over the years of chronic therapy a FH or ASCVD patient typically continues on Repatha.

US wholesale acquisition cost for Repatha is approximately USD 572.70 per 140 mg autoinjector or prefilled syringe, translating to roughly USD 6,875 per year on the 140 mg every-two-weeks regimen or a similar annual cost on the 420 mg monthly regimen. Through the AmgenNow direct-to-patient program launched in 2025, US cash-paying patients can access Repatha at approximately USD 239 per month, or roughly USD 2,868 per year (this program does not extend to international patients, but it sets the floor that has shaped global pricing expectations). The international named-patient acquisition cost for Egyptian patients sits between the AmgenNow US cash-pay price and the regional tender or retail prices and is finalised only on firm-quote issuance. International cold-chain logistics from US source to Cairo typically runs USD 400 to USD 1,500 per shipment. On the insurance side, Bupa Egypt, AXA Egypt, MetLife Egypt, Allianz Egypt, Misr Insurance, and MedGulf Egypt each assess named-patient imports case by case, and Repatha's accessible-end pricing and well-established FH indication make insurer reimbursement more often available than for higher-cost biologics. UHIA coverage for specialty imports is not yet the practical funding path for most patients.

Typical timeline for Repatha in Egypt

For an established FH patient with confirmed genetic or clinical-criteria diagnosis, lipid panels on maximally tolerated statin therapy, and a cardiology or lipidology referral, the typical end-to-end cycle is 5 to 9 weeks. The EDA permit step generally runs 3 to 6 weeks. US-side sourcing through the Amgen authorised distributor network adds approximately 1 to 2 weeks. International cold-chain transit with data-logger inclusion and Egyptian customs clearance under the import permit are typically 4 to 7 days, with the unopened-carton 30-day room-temperature stability envelope providing comfortable slack. Recurring fills on the 140 mg every-two-weeks regimen or the 420 mg monthly regimen run faster once the first fill is complete and the file is on record. Cases involving pediatric HoFH may extend by 1 to 2 weeks for additional documentation review. Timelines are typical ranges, not promises.

What your physician needs to provide

The clinical justification letter for Repatha is the centrepiece of the EDA package. For this product the letter typically includes:

- The confirmed indication: adult HeFH, adult HoFH, adult ASCVD requiring additional LDL-C lowering, adult established CV disease for CV risk reduction, pediatric HeFH from age 10, or pediatric HoFH from age 10
- For FH cases: genetic testing report identifying the pathogenic variant, or clinical-diagnostic criteria (Dutch Lipid Clinic Network or Simon Broome) documentation; for cascade-screening cases, family-history documentation of affected first-degree relatives
- Lipid-panel history documenting LDL-C trajectory on maximally tolerated statin therapy with or without ezetimibe, including the response inadequacy that justifies adding a PCSK9 inhibitor
- For ASCVD secondary-prevention cases: documentation of the qualifying cardiovascular event (myocardial infarction, stroke, coronary revascularisation)
- The dosing schedule chosen: 140 mg subcutaneously every 2 weeks, or 420 mg subcutaneously once monthly (with up-titration to 420 mg every 2 weeks after 12 weeks for HoFH cases with inadequate response); for pediatric patients aged 10 and older, the same regimens apply
- The monitoring plan: LDL-C measurement 4 to 8 weeks after initiation and titration, then periodically per the treating clinician; vigilance for hypersensitivity reactions including angioedema (which require discontinuation); injection-site reaction surveillance; no routine liver function or muscle enzyme monitoring is required by the label, in contrast to high-intensity statin therapy

The treating physician's Egyptian Medical Syndicate membership number and Ministry of Health licence reference anchor the application. Cardiologists, lipidologists, pediatric cardiologists (for FH patients aged 10 to 17), and internal medicine physicians with lipid-clinic experience all have signing authority on personal-import clinical justification letters.

Common questions about Repatha in Egypt

Will Bupa Egypt, AXA, MetLife, or Allianz cover Repatha? Each insurer assesses named-patient imports case by case. Repatha's well-established FH indication and accessible-end pricing

make insurer reimbursement more often available than for higher-cost biologics, but pre-authorisation is typically required. We supply the documentation set the insurer needs; the claim itself remains with you or the dispensing hospital.

My child is 10 and was diagnosed with HeFH through family cascade screening. Is Repatha appropriate? The FDA approved Repatha for pediatric HeFH from age 10 in September 2021. Pediatric eligibility requires the same diagnostic confirmation as adults plus the prescribing pediatric cardiologist's documentation of inadequate response to maximally tolerated statin and ezetimibe. We will not coordinate intake for a patient under the FDA-approved age threshold.

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 Gulf, the UK, or North America. The transparent USD quote means you know exactly what to wire regardless of intra-case EGP movement.

Is there a competitor or alternative? The principal class competitor is alirocumab (Praluent), a Regeneron and Sanofi PCSK9 inhibitor with a similar mechanism and outcomes profile. Inclisiran (Leqvio), a small interfering RNA therapy targeting PCSK9 mRNA, offers a twice-yearly dosing alternative after initial loading. The choice between agents is clinician-driven and based on prior experience, device preference, and continuity of supply.

Can Repatha be self-administered at home? Yes. The 140 mg autoinjector and the 420 mg on-body infusor are designed for patient or caregiver self-administration after training. We coordinate injection training with your home-country prescriber prior to first shipment. The dispensing facility must still be Egyptian-licensed; the carton is handed to the patient from the hospital pharmacy or specialty importer pharmacy, and the patient administers at home.

What is the safety profile? Repatha is generally well tolerated. The most common adverse reactions in clinical trials were nasopharyngitis, upper respiratory tract infection, influenza, back pain, and injection-site reactions. Serious hypersensitivity reactions including angioedema have been reported and require discontinuation.

Where Reserve Meds fits in Repatha cases

Reserve Meds is a US-based concierge coordinator. We do not replace your cardiologist or lipidologist, do not replace EDA, and do not replace the dispensing pharmacy. For Repatha specifically we orchestrate the US-side sourcing through an authorised distributor of Amgen, prepare the regulatory documentation kit your physician needs for the EDA filing (FH or ASCVD indication letter template, lipid-panel summary, dosing schedule, monitoring plan), coordinate the international 2 to 8 degree Celsius cold-chain logistics with data-logger inclusion to Cairo, and run a single named coordinator throughout the case in English and Arabic. We do not coordinate off-label use. For FH families pursuing chronic therapy over years, we structure recurring fill cadence so the next shipment is on its way before the current carton runs out.

Next step

If your cardiologist or lipidologist has decided Repatha is the right next step for your FH or ASCVD case and local stocking or pricing is the bottleneck, the named-patient pathway through EDA is the route. Join the waitlist below and we will confirm eligibility within 24 to 48 hours and route the documentation kit to your physician.

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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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