Roctavian access in Egypt: the EDA personal-import pathway

How adult patients in Egypt with severe hemophilia A access Roctavian, the first AAV5 gene therapy approved in the United States and EU, when the infusion requires travel to a certified treatment centre abroad and the list price is approximately USD 2.9 million.

Last reviewed 2026-05-12 by Reserve Meds clinical and regulatory team. This page describes the personal-import-and-travel-to-treatment pathway for Roctavian for adult patients in Egypt with severe hemophilia A who meet the eligibility profile for the AAV5 gene therapy.

Section 1. Quick orientation

Roctavian (valoctocogene roxaparvovec-rvox) is a one-time intravenous gene therapy for severe hemophilia A in adults, manufactured by BioMarin Pharmaceutical Inc. of San Rafael, California. The modality is an adeno-associated virus serotype 5 (AAV5) vector that delivers a B-domain-deleted human coagulation factor VIII (FVIII) transgene to hepatocytes, where the transgene drives endogenous FVIII production and partially corrects the underlying clotting defect. The US Food and Drug Administration approved Roctavian on 29 June 2023 for adults with severe hemophilia A (FVIII activity less than 1 IU/dL) who do not have pre-existing antibodies to AAV5 (detected by an FDA-approved test) and have no history of FVIII inhibitors. The European Commission granted conditional marketing authorisation on 24 August 2022. Roctavian is not registered with the Egyptian Drug Authority (EDA) for commercial sale, and there is no BioMarin-certified Hemophilia Treatment Centre in Egypt. For Egyptian adults who meet the eligibility profile, the lawful pathway is the EDA personal-import framework under Law No. 151 of 2019 combined with travel to a certified BioMarin treatment centre in the United States or European Union where the infusion is administered. Reserve Meds coordinates eligibility verification, certified-centre booking, frozen-product logistics, and the long-term monitoring framework. **Reserved for you.**

Section 2. Why patients in Egypt need Roctavian through a named-patient pathway

Egypt carries one of the larger hemophilia A patient populations in the Middle East and North Africa. The Egyptian Society of Haemophilia and the patient-community network that has developed around the major treatment centres in Cairo, Giza, and Alexandria support people with bleeding disorders through registries, education, and access advocacy alongside the institutional clinical infrastructure. The standard-of-care reality in Egypt for severe hemophilia A is recombinant or plasma-derived FVIII prophylaxis where supply and funding permit, with emicizumab (Hemlibra) available through named-patient channels and select reimbursed pathways for patients with inhibitors or where prophylactic factor coverage is limited. Roctavian represents a categorically different option: a single intravenous infusion intended to provide multi-year freedom from prophylaxis dosing for patients who meet the eligibility profile.

The structural reasons Egyptian adults pursue Roctavian through a cross-border pathway are concrete. BioMarin has not registered Roctavian with the EDA. There is no certified treatment centre in Egypt because BioMarin's commercial footprint in MENA for this product is limited and the certified-centre training, AAV5 vector handling certification, infusion readiness sign-off, and outcomes warranty infrastructure have not been built locally. Patients in Egypt who meet the eligibility profile (severe hemophilia A with FVIII activity less than 1 IU/dL, AAV5-negative on the FDA-approved companion test, no FVIII inhibitor history, no contraindicating hepatic disease) and who can self-fund or have verified third-party funding must travel to a BioMarin-qualified Hemophilia Treatment Centre in the United States or European Union for the infusion. The EDA personal-import permit facilitates documentation for the cross-border movement of the AAV5 antibody-test sample and any pre- or post-travel supply (factor product the patient brings in transit, corticosteroid prescription filled in Egypt), but the infusion itself takes place at the certified centre abroad. The post-2022 EGP depreciation has made the financial planning particularly demanding, and Egyptian families with diaspora connections in the Gulf, Europe, or North America frequently coordinate the USD funds for the case from across multiple countries.

Section 3. The EDA personal-import pathway and the BioMarin certified-centre pathway for Roctavian

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 issued by Prime Minister Decision No. 777 of 2020 on 29 March 2020. EDA permits the importation of unregistered medicines for a specific patient under defined conditions, most importantly where no equivalent registered product is available locally. The pathway is commonly referred to as Personal Importation, sometimes described in EDA correspondence as Special Access or Compassionate Use for unregistered drugs. The application is filed through the dispensing institution's import pharmacy. Reserve Meds does not file with EDA and does not act as an Egyptian importer of record.

For Roctavian specifically, the dominant pathway is travel-and-infuse abroad rather than import-and-infuse-at-home, because BioMarin does not support infusion outside a qualified Hemophilia Treatment Centre and no such centre exists in Egypt. The EDA framework remains relevant for the patient's pre-infusion AAV5 antibody testing logistics (the FDA-approved companion test may not be available at all Egyptian hematology labs and sample shipment abroad may require import-export documentation), for the post-infusion corticosteroid prescription if filled in Egypt, and for any pre-infusion factor product the patient brings into Egypt in transit. Reserve Meds coordinates the AAV5 sample logistics, the certified-centre booking with the BioMarin RoctavianConnect programme, the patient and family travel logistics, and the handoff between the certified centre's hematology team and the Egyptian-side hematology team for post-travel monitoring.

The cell-specific clinical-justification framework for Roctavian is the gene-therapy eligibility envelope. BioMarin's RoctavianConnect handles the eligibility verification through the certified centre: confirmed severe hemophilia A with FVIII activity less than 1 IU/dL, negative AAV5 neutralising antibody titre on the FDA-approved companion test, no current or historical FVIII inhibitors confirmed through prior medical records (not patient recall alone), baseline liver function tests (ALT, AST, alkaline phosphatase, total bilirubin) within an acceptable range, no significant fibrosis, and no active hepatitis B or C or HIV with uncontrolled viral load. Patients who do not pass any one of these gates are not Roctavian candidates and the conversation routes back to the treating hematologist for continued FVIII prophylaxis or emicizumab. Routine EDA documentation for the parallel logistics elements is typically processed in a 3 to 6 week window

once the package is complete; the certified-centre booking is the rate-limiting layer and runs separately.

Section 4. Where Roctavian gets infused for Egyptian patients

Roctavian is supplied only to a limited network of BioMarin-qualified Hemophilia Treatment Centres (HTCs) that have completed product-specific training, vector handling certification, and infusion readiness sign-off. There are no certified centres in Egypt. For Egyptian adults who meet the eligibility profile, the available infusion locations are HTCs in the United States and in European Union countries where Roctavian is commercially available. The Egyptian-side institutional partners that handle pre-travel eligibility work-up, post-travel monitoring, and corticosteroid management are the major tertiary academic and private hematology centres.

Cairo University Hospitals (Kasr Al Ainy), the oldest and largest academic hospital network in Egypt and the Middle East, with a Drug Information Center, dedicated hematology and oncology units, and an institutional import workflow, is the most experienced public-academic partner for complex bleeding-disorder management. Ain Shams University Hospitals, the second major academic hospital network in Cairo, with strong hematology, hepatology, and pediatric services, holds parallel capacity. On the private super-specialty side, Dar Al Fouad Hospital in 6th of October City, Giza, JCI-accredited since 2005 and part of the Alameda Healthcare Group with active oncology and organ-transplantation infrastructure, supports the kind of complex pre- and post-infusion work-up that Roctavian requires. As-Salam International Hospital in Cairo, one of the most advanced specialty centres in Egypt, the Cleopatra Hospitals Group across multiple Cairo facilities, and the Magdi Yacoub Heart Foundation infrastructure all contribute institutional capacity for specialised hematology services. The Egyptian Society of Haemophilia and the patient-advocacy networks that have developed around these centres can support family education and logistics planning around the travel-and-infuse arc, alongside the clinical institutions handling the medical case.

The travel-and-infuse logistics are demanding. The patient must travel to the certified centre, undergo final pre-infusion confirmation locally at that centre, receive the one-time intravenous infusion over approximately two hours (dose-volume dependent), and remain near the certified centre for weeks of post-infusion corticosteroid management and FVIII expression monitoring before returning to Egypt. Reserve Meds coordinates the certified-centre booking, the patient and family travel logistics, visa documentation flagging where needed, and the handoff between the certified centre's hematology team and the Egyptian-side hematology team for post-travel monitoring.

Section 5. Real cost picture for Roctavian in Egypt

Reserve Meds quotes in US dollars and accepts USD wire transfers. The EGP 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 and a controlled-depreciation outlook through end of year per IMF Article IV consultation forecasts. Quoting in USD insulates the patient from intra-case currency drift, which for a multi-month travel-and-infuse arc is particularly important.

- **Drug cost reference.** US wholesale acquisition cost is approximately USD 2.9 million per patient for the single one-time dose, publicly disclosed by BioMarin at the June 2023 launch and corroborated by FiercePharma, BioPharma Dive, and Managed Healthcare Executive. This is a list price subject to confidential payer-specific net pricing and to the outcomes-

based warranty rebate structure in the US market, neither of which extends to international self-pay patients. EU pricing is country-specific and confidential at the net level; publicly reported German list reference and negotiated reimbursement amounts indicate an order-of-magnitude similar to US WAC. International self-pay patients should be quoted against the US WAC plus the full coordination, travel, infusion-centre, and post-infusion monitoring cost stack, not against a discounted figure. In EGP terms at the prevailing rate the drug-only list price corresponds to approximately EGP 150 to 155 million.

- **International logistics and travel.** Frozen-product logistics from BioMarin to the certified centre run on validated dry-ice or deep-frozen shippers with continuous temperature monitoring; this cost is largely embedded in BioMarin's supply chain to the certified centre rather than in a separate international shipping line to Egypt. The dominant travel-side line items are patient and immediate-family travel (international airfare, accommodation near the certified centre for the multi-week post-infusion monitoring window), local ground transport, visa processing where applicable, and incidentals. A realistic envelope is USD 30,000 to USD 80,000 for the travel-and-stay layer depending on certified-centre location, family configuration, and stay duration.
- **Pre-travel work-up and post-travel monitoring.** AAV5 antibody testing at the FDA-approved companion test, FVIII inhibitor history confirmation, baseline liver function tests, and any imaging required at the Egyptian-side hematology centre (Kasr Al Ainy, Ain Shams, Dar Al Fouad, As-Salam, Cleopatra). Post-travel weekly liver function tests during the corticosteroid taper, then tapering frequency over the first year, FVIII activity monitoring at protocol-defined intervals, hepatocellular carcinoma surveillance per HTC protocol, and bleeding-event tracking. These costs are paid to the Egyptian-side institution and are typically modest relative to the drug and travel layers.
- **Regulatory and concierge.** EDA documentation fees where applicable, Reserve Meds' concierge coordination fee itemised separately on every firm quote.

Egypt's private insurance market does not reimburse a USD 2.9 million one-time gene therapy as a standard line item. Bupa Egypt, AXA Egypt, MetLife Egypt, Allianz Egypt, Misr Insurance, MedGulf Egypt, Orient Takaful, and Royal Insurance each assess named-patient claims case by case, but a gene-therapy price point at this level is not a standard reimbursable line for any local insurer. The Universal Health Insurance Authority (UHIA) does not contemplate Roctavian at the current rollout. Cash-pay funded through patient and family resources, often supplemented by diaspora contribution from relatives in the Gulf, Europe, or North America, is the default posture. BioMarin's US outcomes-based warranty and US copay assistance do not extend to international self-pay patients.

Section 6. Typical timeline for Roctavian in Egypt

Roctavian timelines extend materially beyond the EDA regulatory clock because the certified-centre pathway is the rate-limiting layer. Pre-travel eligibility work-up at an Egyptian hematology centre (AAV5 antibody titre, FVIII activity confirmation, FVIII inhibitor history, baseline liver work-up) typically takes 4 to 8 weeks depending on sample-shipment logistics for the AAV5 companion test if performed abroad and local laboratory scheduling. Certified-centre booking and BioMarin RoctavianConnect verification typically takes 4 to 12 weeks depending on the

centre's capacity and the patient's documentation completeness. Travel preparation, visa processing where required, and family logistics take 2 to 8 weeks running in parallel. The certified-centre stay itself is several weeks, structured around the infusion day and the subsequent corticosteroid-managed monitoring window. Post-return monitoring in Egypt runs for years. A realistic end-to-end planning horizon from first contact to infusion is 3 to 9 months. These ranges are typical, not promises.

Section 7. What your physician needs to provide

For Roctavian the documentation work is the most extensive in the Reserve Meds matrix because both the Egyptian-side hematology team and the BioMarin certified centre require comprehensive medical records. The Egyptian-side treating hematologist provides the patient identifier, the severe hemophilia A diagnosis with FVIII activity confirmed less than 1 IU/dL, the FVIII inhibitor history confirmed negative through prior medical records (Bethesda titre history where available, not patient recall alone), the bleeding-event history and any prophylaxis regimen the patient is on (recombinant or plasma-derived FVIII, emicizumab), baseline liver function tests (ALT, AST, alkaline phosphatase, total bilirubin), any history of hepatic disease, hepatitis B or C status, HIV status with viral load if positive, and the rationale for selecting Roctavian over continued FVIII prophylaxis or emicizumab.

The AAV5 neutralising antibody titre on the FDA-approved companion test is a hard pre-gate; the result must be in hand and negative before any certified-centre booking is initiated. The Egyptian hematologist coordinates the sample collection and submission to the laboratory performing the FDA-approved test. The corticosteroid management plan is structured around the BioMarin label, which prescribes a prophylactic or reactive corticosteroid regimen (typically oral prednisone or equivalent) initiated based on ALT trends and tapered over weeks to months, individualised by the certified centre and continued under the Egyptian hematologist's supervision after return. The Egyptian hematologist's Egyptian Medical Syndicate (EMS) membership number and Ministry of Health licence reference are on every document; the certified centre's hematology team provides parallel documentation under their own institutional credentials. Pharmacovigilance reporting through the Egyptian Pharmacovigilance Center (EPVC) for the long-running post-infusion monitoring stays with the treating hematologist in Egypt.

Section 8. Common questions about Roctavian in Egypt

Will Bupa Egypt, AXA Egypt, MetLife, or Allianz cover this? A USD 2.9 million one-time gene therapy is not a standard reimbursable line item for any Egyptian private insurer. Each insurer assesses named-patient claims case by case, but coverage of a gene therapy at this price point is not standard practice in the Egyptian market. We do not promise coverage.

Does UHIA cover Roctavian? No. The UHI rollout is phased through 2032 and does not contemplate gene therapy at this price band. The funding path is cash-pay or family-pooled cash-pay, often supplemented by diaspora contribution from relatives in the Gulf, Europe, or North America.

Can I be infused in Egypt? No. BioMarin does not support infusion outside a qualified Hemophilia Treatment Centre, and there are no qualified centres in Egypt. The infusion takes place at a certified centre in the United States or European Union, with travel, accommodation, and weeks of post-infusion monitoring at the centre as a non-negotiable part of the pathway.

Will my Kasr Al Ainy, Ain Shams, or Dar Al Fouad hematologist's letter be sufficient? The Egyptian hematologist's clinical documentation is essential for the pre-travel work-up and post-

travel monitoring, and feeds the certified centre's eligibility verification. The certified centre's own hematology team performs final pre-infusion confirmation and runs the infusion-day care; the case is genuinely co-managed across borders.

What is the safety profile? The most common adverse reactions in the GENEr8-1 phase 3 trial were transient ALT elevation, headache, nausea, vomiting, fatigue, abdominal pain, and infusion-related reactions. The dominant safety signal is hepatic transaminase elevation requiring corticosteroid management. There is a theoretical long-term risk of hepatocellular carcinoma related to AAV vector integration; no causal cases have been reported in the trial programme, and the label requires long-term hepatic surveillance.

What is the durability picture? Roctavian is not pitched as a cure. GENEr8-1 follow-up published in NEJM and subsequent journal updates show that FVIII expression declines over time in many patients. At five years, 80.8 percent of participants remained off regular prophylaxis, and modelled median time-to-return-to-prophylaxis ranged from 6.4 to 16.1 years. The honest framing for Egyptian patients and families: meaningful but not permanent benefit for most, with a real possibility of returning to factor replacement therapy within a decade.

How does Roctavian compare to emicizumab? Standard of care alternatives are recombinant FVIII prophylaxis and emicizumab (Hemlibra, Roche/Genentech), a bispecific antibody dosed subcutaneously. Hemlibra is a long-running maintenance therapy, broadly available including in jurisdictions where Roctavian is not registered, and suitable for patients with inhibitors. Roctavian offers the prospect of multi-year freedom from prophylaxis dosing for eligible patients. The choice is the treating hematologist's; Reserve Meds does not steer the decision.

Section 9. Where Reserve Meds fits in Roctavian cases

Reserve Meds is a US-based concierge coordinator. We do not replace your hematologist, do not replace BioMarin's RoctavianConnect programme, do not replace the certified treatment centre, and do not replace the EDA. For Roctavian specifically, the orchestration we provide is eligibility verification coordination between the Egyptian-side hematologist and BioMarin's RoctavianConnect, AAV5 antibody testing logistics where the FDA-approved companion test is performed abroad, certified-centre booking and the parallel scheduling of pre-travel and travel logistics, support to the family on the travel-and-stay layer including USD coordination across diaspora-based relatives, and the documentation framework that hands off between the certified centre's hematology team and the Egyptian-side hematology team for post-travel monitoring. The Egyptian Society of Haemophilia and the patient-advocacy networks around Kasr Al Ainy, Ain Shams, Dar Al Fouad, and the Cleopatra group can run alongside the medical and logistics coordination; Reserve Meds works with these networks rather than in place of them. Operating notes that bind the coordinator: AAV5 neutralising antibody titre is a hard pre-gate; FVIII inhibitor history is confirmed from records not recall; infusion is at the certified centre, not in Egypt; durability is framed honestly; no off-label use; no pediatric coordination; no coordination for patients with active hepatic disease without explicit treating-centre sign-off. No prior Reserve Meds case experience exists for Roctavian at the date of this page. Standard NPP coordination applies with the gene-therapy-specific operating notes above as binding.

Section 10. Next step

If your hematologist has identified Roctavian as a possible option for severe hemophilia A and you are based in Egypt, the next step is the waitlist. We confirm eligibility within 24 to 48 hours,

route the conversation to a structured pre-travel work-up, and align with your hematology centre on the documentation framework. **Reserved for you.**

This guide is informational, not medical or legal advice. The EDA personal-import framework and the BioMarin certified-centre pathway both require licensed clinical judgment; Reserve Meds is the coordinator, not the prescriber or the infusion centre.

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Last medically reviewed: 2026-05-12.