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

How patients in Egypt aged 6 and older access Alyftrek (vanzacaftor/tezacaftor/deutivacaftor) for cystic fibrosis when the medicine is not yet locally registered, with attention to the boxed warning on drug-induced liver injury and the CFTR genotype eligibility requirement.

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1. Quick orientation

Alyftrek is the brand name for vanzacaftor/tezacaftor/deutivacaftor, a next-in-class oral once-daily fixed-dose triple combination cystic fibrosis transmembrane conductance regulator (CFTR) modulator developed and commercialized by Vertex Pharmaceuticals. The US Food and Drug Administration approved Alyftrek on 20 December 2024 for the treatment of cystic fibrosis (CF) in patients aged 6 years and older who have at least one F508del mutation or one of approximately 94 other responsive mutations in the CFTR gene. The Alyftrek label covers approximately 31 additional non-F508del mutations that are not on the Trikafta label, expanding eligibility for highly effective CFTR modulator therapy. In Egypt, Alyftrek is not yet registered with the Egyptian Drug Authority (EDA); patients reach the medicine through EDA Personal Importation under Law No. 151 of 2019. Reserved for you.

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

Cystic fibrosis is less common in Egypt than in the Gulf countries where consanguinity rates and population-specific founder CFTR variants drive higher prevalence, but Egyptian pediatric pulmonology programmes do see CF cases. The Egyptian Society of Pediatric Pulmonology has built CF diagnostic and follow-up capacity at the major academic centres, and Egyptian CF cohorts have been described in the pediatric pulmonology literature, including patients with F508del and non-F508del responsive mutations. Alyftrek sits in the third pattern of EDA access gap: not registered locally at all. Vertex is the sole commercial supplier of CFTR modulator therapy worldwide, and outside the United States, EU, and UK (where Alyftrek received MHRA approval in March 2025 and European Commission authorisation on 1 July 2025), national reimbursement and routine commercial stocking continue to lag the regulatory timeline. UAE MOHAP, Saudi SFDA, Egypt EDA, India CDSCO, and most other authorities in the region have not completed national review and routine commercial stocking as of this page's review date.

Three patterns drive Egyptian Alyftrek demand. First, eligibility expansion: patients carrying one of the approximately 31 CFTR mutations covered by Alyftrek but not Trikafta now have a label-supported option, and the personal-import pathway is the only available route. Second, switch demand: patients already established on Trikafta who would benefit from once-daily dosing (pediatric families, adolescents, adults with adherence challenges) sometimes elect to pursue Alyftrek through personal importation. Third, expatriate and second-opinion cases: Egyptian CF patients seen at international expert centres or with adult children in the Gulf, the UK, or the US, who coordinate USD funds and Arabic-English correspondence in parallel. Substitution to a non-CFTR modulator is not a clinical option; CFTR modulator therapy fundamentally changes the disease trajectory for eligible patients and there is no non-Vertex competitor in the class.

3. The EDA named-patient pathway for Alyftrek

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 Alyftrek includes the clinical justification letter from the treating pediatric pulmonologist or CF specialist, on hospital letterhead, original and stamped, stating the cystic fibrosis diagnosis (sweat chloride result with reference values, CFTR genotype with both alleles documented), the confirmation that the patient's genotype matches the Alyftrek label table (at least one F508del or one of the approximately 94 other responsive mutations), the patient's age (6 years or older), and the specific reason this product is required (CFTR modulator therapy as standard of care, with the once-daily regimen indicated, or eligibility expansion for non-Trikafta-covered mutations); a recent prescription specifying brand name (Alyftrek), generic name (vanzacaftor/tezacaftor/deutivacaftor), the weight-banded tablet strength, and quantity required (the typical 28-day pack is the commercial unit); a patient identifier (copy of the national ID card or passport, and for pediatric cases the guardian identifier); the treating physician's Egyptian Medical Syndicate (EMS) membership number and Ministry of Health licence reference; product details (Vertex Pharmaceuticals Incorporated as US NDA holder, country of origin, FDA approval reference, room-temperature storage condition); the destination dispensing facility licence; and a chain-of-custody plan.

The clinical-justification angle that matters most for Alyftrek is the CFTR genotype confirmation against the label table. The treating physician documents both alleles and references the Alyftrek FDA label mutation list. Where the patient is currently on Trikafta and switching to Alyftrek, the letter documents the rationale (once-daily simpler dosing for pediatric or adolescent adherence; broader mutation coverage; non-inferiority on percent predicted FEV1 through week 24 and superiority on sweat chloride reduction per SKYLINE 102 a