Ojemda access in Egypt

A once-weekly oral type II RAF inhibitor for relapsed or refractory BRAF-altered pediatric low-grade glioma, reached through the Egyptian Drug Authority Personal Importation pathway.

Quick orientation

Ojemda (tovorafenib) is a brain-penetrant type II RAF inhibitor developed by Day One Biopharmaceuticals and approved by the US FDA on April 23, 2024 for patients 6 months of age and older with relapsed or refractory pediatric low-grade glioma (pLGG) harbouring a BRAF fusion, rearrangement, or BRAF V600 mutation, who have received at least one prior line of systemic therapy. It was the first systemic therapy ever approved by the FDA for pediatric LGG with BRAF rearrangements, including the common KIAA1549-BRAF fusion. In Egypt, Ojemda is not yet registered with the Egyptian Drug Authority (EDA). For Egyptian children whose pediatric neuro-oncologist has confirmed a BRAF alteration and documented progression on at least one prior systemic therapy, the lawful route is the EDA Personal Importation pathway, supported by a US specialty pharmacy procurement chain and named-patient documentation prepared in coordination with the dispensing institution. Reserve Meds coordinates the US sourcing, the documentation kit your child's neuro-oncologist will need, and the international logistics on the family's behalf, while clinical decisions stay with your treating pediatric oncology team. Reserved for you.

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

Pediatric low-grade glioma is rare in absolute terms, and the international payer and regulatory systems move slowly on orphan pediatric oncology launches. The Egyptian Drug Authority has not yet listed Ojemda on the national registration list. Egyptian families with a child diagnosed with BRAF-altered relapsed or refractory pLGG cannot fill the prescription locally because the product is not registered, not stocked, and not on any reimbursement list in Egypt as of this page's review date.

The alternatives, in the absence of Ojemda, are off-label use of adult RAF or MEK inhibitors not designed or labeled for pediatric pLGG, chemotherapy regimens with established pediatric toxicity profiles, or watchful waiting after a documented progression. For BRAF V600-mutant pLGG specifically, dabrafenib plus trametinib is an FDA-approved alternative with a pediatric indication. For BRAF fusion or rearrangement pLGG (the more common molecular setting, dominated by KIAA1549-BRAF), Ojemda was the first FDA-approved systemic therapy and remains the clearest on-label option. The EDA Personal Importation framework, codified by Law No. 151 of 2019, is the lawful route when a recognised reference authority has approved a medicine and no clinically equivalent locally registered alternative is suitable for the named patient. For pediatric oncology in Egypt, Children's Cancer Hospital Egypt 57357 is the natural fit, as the largest pediatric oncology hospital in the world by bed count, with established named-patient import workflow and the only pharmacogenetics unit of its kind in Egypt and the Arab world.

The EDA named-patient pathway for Ojemda

The Egyptian Drug Authority (EDA) was created by Law No. 151 of 2019, with executive regulations issued under Prime Minister Decision No. 777 of 2020. EDA permits importation of unregistered medicines for a specific named patient where no equivalent registered product is available locally or where the available quantity of an equivalent locally registered product cannot meet the patient's clinical need. The pathway is commonly referred to as Personal Importation and described in EDA correspondence as Special Access or Compassionate Use for novel pediatric agents.

For an Ojemda case, applications are filed through the dispensing institution's import pharmacy. The standard package includes the clinical justification letter from the treating pediatric neuro-oncologist on hospital letterhead (the relapsed or refractory pLGG diagnosis, the molecular confirmation of a BRAF fusion, rearrangement, or V600 mutation by an FDA-approved companion diagnostic or other validated next-generation sequencing assay, the imaging documentation of disease, prior systemic therapy with named regimens and documented outcomes, the clinical rationale for tovorafenib, the BSA-weighted dose, planned course duration, and the pediatric-specific monitoring plan), a recent prescription specifying brand name (Ojemda), generic name (tovorafenib), presentation (100 mg tablet or 25 mg/mL oral suspension), and the per-cycle quantity, the patient identifier copy (national ID card or passport), the treating pediatric oncologist's Egyptian Medical Syndicate membership number and Ministry of Health licence reference, product details (Day One Biopharmaceuticals, Inc. as US manufacturer of record; country of origin; FDA approval reference; shelf life; room-temperature storage for tablets and refrigerated storage for reconstituted oral suspension per the package insert), the destination dispensing facility licence, and a chain-of-custody plan covering transit to the receiving Egyptian pharmacy through Cairo International Airport.

The clinical-justification angle specific to Ojemda is the BRAF molecular confirmation. EDA reviewers will look for the named-patient molecular report (FoundationOne CDx, or another validated NGS panel, identifying the specific BRAF fusion such as KIAA1549-BRAF, other BRAF rearrangement, or the V600 mutation) and for documentation of prior-line failure on at least one systemic therapy. The dosing plan is BSA-weighted (380 mg per square meter once weekly, with the maximum recommended dose of 600 mg once weekly capping exposure for larger pediatric patients) and the pediatric dose tables in the FDA label translate BSA bands into either tablet count or suspension volume. The monitoring plan covers liver function tests, complete blood counts, serum creatine phosphokinase, dermatologic assessments, photosensitivity counseling, and pediatric-specific monitoring of growth and pubertal development given the duration of therapy.

Routine EDA personal-import authorisations for well-documented pediatric oncology cases typically process in a 3 to 6 week window once a complete package is submitted. Pediatric cases routed through Children's Cancer Hospital Egypt 57357 with their established workflow may run at the faster end of the range. EDA reserves discretion at every step. Reserve Meds does not promise EDA timelines and is not the filer.

Where Ojemda gets dispensed in Egypt

Ojemda is a pediatric oral therapy with room-temperature tablet handling and refrigerated handling for the reconstituted oral suspension. The dispensing-facility shortlist is narrower than for an adult ambient-temperature oral because of the pediatric neuro-oncology specialty and caregiver counseling load that the suspension presentation requires. The institutions that handle

EDA named-patient imports as routine workflow and have pediatric neuro-oncology capability include Children's Cancer Hospital Egypt 57357 (CCHE 57357) as the natural primary fit, the pediatric oncology units at Cairo University Hospitals (Kasr Al Ainy), the pediatric oncology service at Ain Shams University Hospitals, the pediatric services at Dar Al Fouad Hospital, and the pediatric units at As-Salam International Hospital. Children's Cancer Hospital Egypt 57357 opened in 2007, is the largest pediatric oncology hospital in the world by bed count, and houses the Personalized Medication Management Unit (the first pharmacogenetics unit of its kind in Egypt and the Arab world), which positions it as the institutional center of gravity for BRAF-altered pLGG cases.

For families whose treating pediatric neuro-oncologist is at a regional hospital outside Cairo, Giza, or Alexandria, the practical route is to co-manage the case with one of the institutions above. A Cairo-based licensed specialty importer typically handles the EDA filing and customs clearance through Cairo International Airport, with delivery to the receiving institutional pharmacy. The importer holds the dispensing pharmacy licence; the clinical justification letter still originates with the treating pediatric neuro-oncologist, with weight and BSA-adjusted dosing.

Real cost picture for Ojemda in Egypt

Reserve Meds quotes Egyptian cases in USD and accepts USD wire transfers. The transparent cost build for an Ojemda case has three line items. First, the underlying US drug cost. Ojemda's US wholesale acquisition cost has been reported at approximately USD 33,916 for a 28-day supply across both the 100 mg tablet (16-count) and the 300 mg / 12 mL oral suspension presentations per Day One regulatory filings, putting list-price reference in the range of roughly USD 33,000 to USD 35,000 per 28-day cycle, or annualised list of roughly USD 440,000 before any patient-assistance, payer rebate, or discount adjustment. International named-patient quoted pricing reflects US WAC plus international logistics, documentation, and coordination. Second, international logistics from US source to Cairo International Airport, which for an ambient-temperature oral product (tablet presentation) or a refrigerated handoff for the reconstituted suspension typically runs USD 400 to USD 1,000 per shipment. Third, regulatory documentation handling fees at the Egyptian end and the Reserve Meds concierge fee, itemised on the firm quote rather than bundled.

Many Egyptian families coordinate USD funds through relatives in the Gulf, the UK, or North America, which is helpful given the EGP has lost more than 70 percent of its value against the US dollar since early 2022 (USD/EGP near 52 to 53 in May 2026 per IMF Article IV consultation). On the insurance side, Bupa Egypt, AXA Egypt, MetLife Egypt, and Allianz Egypt handle named-patient imports case by case, with private plans more likely to engage where pediatric oncology is a recognised covered indication. Misr Insurance, Orient Takaful, and selected family or employer-linked plans may engage on a case basis. UHIA coverage of specialty imports remains constrained across most governorates in the current rollout phase. Cash-pay is the default operating posture; reimbursement, where it applies, is sought after delivery through the patient or hospital's claim. Day One's US patient assistance mechanisms (EveryDay Support From Day One) do not extend to international patients.

Typical timeline for Ojemda in Egypt

End to end, a routine Ojemda case at a tertiary pediatric center with established EDA personal-import workflow typically clears 3 to 6 weeks of EDA review, plus three to seven days for US specialty pharmacy intake and outbound preparation (Ojemda is dispensed through Biologics by

McKesson or Onco360 under Day One's limited distribution architecture), plus four to seven days for international transit and customs clearance at Cairo International Airport. That puts a realistic end-to-end planning window of four to eight weeks for the first shipment. Because the tablet presentation is room-temperature stable, the international transit leg does not require a validated cold-chain shipper; the reconstituted suspension is handled refrigerated once prepared, so most shipments move ambient with caregiver-side reconstitution per the package insert. The once-weekly dosing schedule is a meaningful pediatric advantage because each shipment covers a longer treatment interval per gram of supply than a daily oral oncolytic would impose.

What your physician needs to provide

The cornerstone document is the clinical justification letter, original and stamped on hospital letterhead, signed by the treating pediatric neuro-oncologist under their active Egyptian Medical Syndicate membership and Ministry of Health licence. For Ojemda, the letter typically covers the relapsed or refractory pLGG diagnosis with the supporting imaging, the molecular report confirming a BRAF fusion, rearrangement, or V600 mutation by an FDA-approved companion diagnostic (FoundationOne CDx) or other validated NGS assay, the prior systemic therapy with named regimens and documented outcomes, and the clinical rationale for tovorafenib. The dosing plan is stated (380 mg per square meter once weekly, with the maximum recommended dose of 600 mg once weekly, with reference to the FDA pediatric dose table that translates BSA bands into tablet count or suspension volume). The monitoring plan covers liver function tests, complete blood counts, serum creatine phosphokinase, dermatologic assessments, photosensitivity counseling, and pediatric-specific monitoring of growth and pubertal development given the duration of therapy. Caregiver counseling on suspension reconstitution and timing also belongs in the documentation kit because Reserve Meds operationally needs the caregiver to be onboarded for the suspension presentation in the youngest patients.

The treating pediatric neuro-oncologist's EMS membership and Ministry of Health licence must be active for the full requested treatment course. The dispensing facility's institutional pharmacy licence is the second pillar of the application. Public-sector pediatric oncologists at Children's Cancer Hospital Egypt 57357, Kasr Al Ainy, and Ain Shams, and private-sector pediatric oncologists at Dar Al Fouad, As-Salam, and similar institutions have signing authority on EDA personal-import clinical justification letters. Reserve Meds supplies the physician documentation kit, including the Egyptian Pharmacovigilance Center (EPVC) adverse-event reporting reference. Reserve Meds does not file adverse-event reports; that responsibility sits with the treating clinician under their Egyptian licence.

Common questions about Ojemda in Egypt

Will Bupa Egypt, AXA Egypt, MetLife, or Allianz cover Ojemda?
Each insurer assesses named-patient pediatric imports case by case. Some plans engage where pediatric oncology is documented as a covered category and the BRAF molecular confirmation is in hand. Pre-authorisation is the norm. Reserve Meds supplies the documentation; the claim filing remains with the family or hospital. Cash-pay is the default posture for pediatric named-patient cases in Egypt.

Does UHIA cover Ojemda?
Not as a general rule. The UHIA rollout is phased through 2032 and does not currently cover most specialty pediatric imports.

Is BRAF testing required before starting?
Yes. The FDA indication is for patients whose tumor harbours a BRAF fusion, rearrangement, or V600 mutation. Molecular testing (FoundationOne CDx is the FDA-approved companion diagnostic, with other validated NGS assays in clinical use) is the gate to candidacy and is the first item the EDA reviewer will look for in the clinical justification packet.

Can my child take Ojemda at home?
Yes. Ojemda is an oral therapy dosed once weekly, with a tablet presentation (100 mg) for older children and a reconstituted oral suspension (25 mg/mL) for younger children including those down to six months. Caregivers prepare the suspension per the package insert. The dispensing point must be a licensed Egyptian pharmacy; direct-to-home delivery without a licensed dispensing facility in the chain is not the model.

What is the safety profile we should expect?
The FDA label identifies the most common adverse reactions in the FIREFLY-1 population as hair color changes, rash, fatigue, viral infection, vomiting, headache, pyrexia, dry skin, constipation, nausea, dermatitis acneiform, and upper respiratory tract infection. Laboratory abnormalities of note include changes in liver enzymes, increased creatine phosphokinase, and hematologic shifts. Skin and hair effects, including depigmentation and photosensitivity, are characteristic of RAF inhibitors as a class. Your pediatric oncologist will review the full profile with the family before starting.

What is the typical course duration?
The label specifies continuation until disease progression or unacceptable toxicity. FIREFLY-1 reported median duration of response of 16.6 months as a clinical reference point. Individual treatment course length is determined by the treating pediatric oncologist based on response and tolerability.

Why Ojemda and not dabrafenib plus trametinib?
The choice is driven by molecular profile. Patients with BRAF fusion or rearrangement (most commonly KIAA1549-BRAF) are not candidates for dabrafenib plus trametinib in the same way as V600-mutant patients. Ojemda's type II RAF mechanism is designed to address the dimer-dependent signaling that BRAF fusions drive. The decision rests with the treating pediatric neuro-oncologist.

Our family is split between Cairo and the Gulf. Can you coordinate in both places?
Yes. Reserve Meds runs the patient and family coordination in Arabic where requested and the family-side correspondence in English in parallel, with a single named coordinator across the Egyptian diaspora.

Where Reserve Meds fits in Ojemda cases

Reserve Meds is a US-based concierge coordinator. We do not replace your pediatric oncologist, do not replace EDA, do not replace your dispensing pharmacy, and we do not act as an Egyptian importer of record. For an Ojemda case in Egypt, we orchestrate the US specialty pharmacy procurement through Day One's limited distribution partners (Biologics by McKesson and Onco360), prepare the documentation kit your pediatric neuro-oncologist needs for the EDA Personal Importation filing including the BRAF molecular report and pediatric-specific dosing detail, coordinate international shipping with full customs documentation through Cairo International Airport, and stay with the case through reorders under a single named coordinator in English and Arabic. No prior Reserve Meds Ojemda case experience is on file in Egypt as of this page's review date; the drug appears on the Reserve Meds drug index with cells published

for Bangladesh, Saudi Arabia, and Turkey, which means the operational playbook is in place. Standard EDA named-patient pediatric coordination applies. The operational profile (small molecule, oral, once-weekly, room-temperature tablet or refrigerated reconstituted suspension, no REMS) is logistically forgiving relative to monoclonal antibody and cell therapy cases. Clinical decisions remain with your pediatric neuro-oncologist. The regulatory authority remains EDA. The dispensing remains with the licensed Egyptian pharmacy.

Next step

If your family is exploring Ojemda for a child whose pediatric neuro-oncologist has confirmed a BRAF alteration in relapsed or refractory pLGG and documented prior-line failure on at least one systemic therapy, the next step is to join the waitlist. We will confirm eligibility and case fit within 24 to 48 hours, send a documentation kit to your treating pediatric oncology team in English with Arabic-language caregiver-facing summaries where requested, and align with Children's Cancer Hospital Egypt 57357 or your institution's import pharmacy on the EDA filing.

Reserved for you.

Related

- Ojemda drug overview
- Egypt country guide
- EDA Personal Importation pathway
- Ojemda in Saudi Arabia
- Ojemda in the UAE
- Pediatric low-grade glioma

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 ›
Last medically reviewed: 2026-05-12.