

[Skip to main content](#)

[Home](#) / [Drugs](#) / [Ojemda](#) / [In Saudi Arabia](#)

Ojemda access in Saudi Arabia

The first systemic therapy for pediatric BRAF-altered low-grade glioma, dosed once weekly, reached through the SFDA Personal Importation Program.

Quick orientation

Ojemda (tovorafenib) is an oral, brain-penetrant, type II pan-RAF kinase inhibitor from Day One Biopharmaceuticals, granted accelerated approval 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) harboring a BRAF fusion or rearrangement, or a BRAF V600 mutation, who have received at least one prior line of systemic therapy. It is the first systemic therapy ever approved by the FDA for pediatric LGG with BRAF rearrangements, including the KIAA1549-BRAF fusion that drives a substantial share of pediatric LGG cases. In Saudi Arabia, Ojemda is not on the SFDA register; the lawful route for Saudi families whose child's pediatric neuro-oncology team has confirmed the BRAF alteration and identified Ojemda as the right next step is the SFDA Personal Importation Program (PIP), routed through the institution's import pharmacy. Reserve Meds coordinates US specialty pharmacy procurement (Biologics by McKesson or Onco360), the SFDA documentation kit, and international logistics tuned to the tablet and oral suspension presentations. Reserved for you.

Why patients in Saudi Arabia need Ojemda via the named-patient pathway

Pediatric low-grade glioma is rare in absolute terms. International payer systems and national formularies move slowly on orphan pediatric oncology launches, and most jurisdictions outside the US and the EU have no national registration for tovorafenib. As of this page's review date, SFDA does not list a local registration for Ojemda. For Saudi families whose child has confirmed BRAF fusion, rearrangement, or V600 mutation pLGG and has progressed on prior therapy, the local alternative is 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 on a slowly progressing tumor.

Ojemda fills the gap with three combined features that no Saudi-market alternative offers: a labeled pediatric indication starting at age 6 months, an on-mechanism action against BRAF-fusion-driven dimer signaling (a profile that distinguishes it from dabrafenib plus trametinib, which is the alternative for BRAF V600-mutant patients but not for the more common BRAF fusion population), and a once-weekly oral schedule that materially reduces caregiver burden compared to a daily oral oncolytic. The SFDA Personal Importation Program is designed for exactly this case shape: an FDA-approved orphan pediatric oncology drug, a confirmed molecular indication, and a treating pediatric neuro-oncologist filing under their SCFHS license.

The SFDA Personal Importation Program for Ojemda

The SFDA Personal Importation Program allows a KSA-licensed physician to request import of a specific medicine for a specific named patient when the medicine is approved by a recognized reference authority and a clinically equivalent locally registered alternative is not suitable. The

framework explicitly contemplates pediatric specialty therapies. Applications are filed through the dispensing institution's import pharmacy and reviewed by SFDA's Drug Sector, with named-patient transactions increasingly routed through the Ghad digital platform.

For an Ojemda case, the application package contains the clinical justification letter from the treating pediatric neuro-oncologist (diagnosis of pediatric low-grade glioma with ICD-10 coding, the molecular result confirming BRAF fusion, rearrangement, or V600 mutation, the companion-diagnostic context including FoundationOne CDx or a validated next-generation sequencing assay, the imaging history and progression on prior therapy, the requested dose and duration), SCFHS license verification, an SFDA-format anonymized pediatric patient identifier with parental or guardian consent on file at the institution, product details (Ojemda 100 mg tablets or 25 mg/mL oral suspension as appropriate to the patient's age and swallowing ability, Day One Biopharmaceuticals as US license holder, country of origin, requested quantity, lot, expiry), the destination dispensing facility license, and a chain-of-custody plan covering room-temperature tablet handling and refrigerated suspension handling per the package insert.

The clinical-justification angle specific to Ojemda is the confirmatory molecular testing: SFDA reviewers expect to see the BRAF alteration documented on a validated assay before approving a pediatric RAF inhibitor case. The treating pediatric neuro-oncologist's letter typically names the assay used, the specific alteration (KIAA1549-BRAF fusion is the most common; other BRAF fusions, BRAF rearrangements, and BRAF V600 mutations are also on-label), the prior systemic therapy lines with progression documentation, the weight or body surface area-based once-weekly dosing plan (380 mg/m² once weekly with a 600 mg cap, with pediatric dose tables in the label translating BSA bands into tablet count or suspension volume), and the monitoring plan. Pediatric-specific monitoring of growth and pubertal development is recommended given the duration of therapy and the patient age band; photosensitivity counseling and sun protection are standard.

Approval timelines for routine pediatric oncology cases at established pediatric programs typically run 10 to 21 business days. First-time pediatric RAF inhibitor cases at a given institution may extend to four to six weeks while the pediatric oncology pharmacy team aligns with SFDA on the molecular evidence threshold.

Where Ojemda gets dispensed in Saudi Arabia

Ojemda is dispensed through institutions with established pediatric oncology and pediatric neuro-oncology capability and named-patient import pharmacy workflow. The operative institutions in the Kingdom are King Faisal Specialist Hospital and Research Centre (KFSH&RC), which carries the comprehensive pediatric cancer center of choice for many tertiary cases with operations in Riyadh, Jeddah, and Madinah; King Abdulaziz Medical City (KAMC) and the Ministry of National Guard Health Affairs network (MNGHA) pediatric oncology services in Riyadh and Jeddah; King Saud University Medical City (KSUMC) pediatric service; and Dr. Sulaiman Al Habib Medical Group (HMG) pediatric specialty services. KFSH&RC and KAMC carry the pediatric neuro-oncology and pediatric pharmacy compounding infrastructure that an Ojemda case requires, particularly for the youngest patients in the approved age band who need the 25 mg/mL oral suspension presentation.

For pediatric patients outside Riyadh and Jeddah, partnering with an SFDA-licensed specialty importer in one of those two cities and routing care through one of the named pediatric centers is the practical model. Because Ojemda tablets are room-temperature stable and the suspension is refrigerated per the package insert, international logistics are wider in tolerance than for a

cold-chain biologic, but the suspension presentation still requires refrigerated handling on the destination leg.

Real cost picture for Ojemda in Saudi Arabia

The transparent cost build for an Ojemda case has three line items. First, the underlying US drug cost. Day One Biopharm