Aptiom

Saudi Arabia · access guide

How to access Aptiom for partial-onset (focal) epilepsy from Saudi Arabia: 2026 pathway via KFSHRC, King Saud Medical City, and the wider kingdom neurology network

By Reserve Meds clinical & regulatory team. Last reviewed 2026-05-20.

Saudi Arabia has the deepest comprehensive epilepsy programme in the wider region at King Faisal Specialist Hospital and Research Centre (KFSHRC) Riyadh, with parallel adult and paediatric neurology services at King Saud Medical City Riyadh, Prince Sultan Military Medical City, King Khalid University Hospital, King Fahad Medical City, King Abdulaziz Medical City National Guard, KFSHRC Jeddah, and the private Dr Sulaiman Al Habib neurology network. The KFSHRC epilepsy programme runs video-EEG monitoring, neurosurgical evaluation, and the full antiepileptic-drug formulary, and has authored the Saudi clinical consensus statements on focal epilepsy management. Aptiom (eslicarbazepine acetate; the international Zebinix brand is the same molecule from Bial) is the third-generation sodium-channel inhibitor in the dibenzazepine family, once-daily, with a cleaner enzyme-induction and hyponatraemia profile than carbamazepine or oxcarbazepine. For a Saudi-resident adult or paediatric patient aged 4 or over with confirmed partial-onset seizures who has either failed an initial first-line antiepileptic or is moving off carbamazepine or oxcarbazepine for tolerability reasons, the operational question is which prescribing centre fits the case, how the SFDA-listed Zebinix supply reaches the dispensing pharmacy, what the insurance pre-authorisation conversation looks like, and how the monthly refill cycle and serum sodium monitoring schedule settle into a Saudi family's life.

This page explains how the pathway works in 2026 for a Saudi-resident patient: who qualifies, where the neurologist or epileptologist conversation happens, where the prescription is written and filled, what the realistic out-of-pocket exposure band is in SAR, what to monitor on therapy (serum sodium being the distinctive concern), and how the longer-term treatment course fits into a Saudi family's life. It is concierge documentation written for a family that is already in conversation with a treating neurologist and wants the operational reality laid out plainly.

Why Aptiom, and why now

Aptiom is eslicarbazepine acetate, a once-daily oral voltage-gated sodium channel blocker. The molecule is a prodrug that is rapidly hydrolysed after absorption to eslicarbazepine, the active S-enantiomer of the carbamazepine 10-monohydroxy metabolite. Developed by Bial (Portugal), commercialised internationally as Zebinix, and licensed to Sunovion as Aptiom for the US market.

The FDA approved Aptiom in November 2013 as adjunctive therapy for adult partial-onset seizures, expanded to monotherapy in September 2015, and expanded to paediatric patients aged 4 and over in September 2017. The EMA approved Zebinix in April 2009. The pivotal Phase 3 programme demonstrated median seizure reduction of approximately 35 to 45 percent at the 1,200 mg/day adjunctive dose, with responder rates of 35 to 45 percent versus 14 to 22 percent for placebo.

For a Saudi patient who has trialled levetiracetam or lamotrigine without adequate seizure control, or who is moving off carbamazepine because of hyponatraemia or unfavourable interactions, Aptiom (or its international equivalent Zebinix) is the operational answer that combines once-daily dosing, a cleaner enzyme-induction profile than carbamazepine, and lower hyponatraemia incidence than oxcarbazepine in head-to-head comparisons.

What Aptiom is, in plain language

Aptiom is an oral tablet, taken once daily, with or without food, at approximately the same time each day. Tablets are available in 200 mg, 400 mg, 600 mg, and 800 mg strengths. Tablets may be crushed if swallowing is difficult. Storage is room temperature; no refrigeration required. There is no infusion, no inpatient stay, no certified-centre requirement.

The adult titration schedule starts at 400 mg once daily for one week, increases to 800 mg once daily for the second week, with most adults maintained at 800 mg or 1,200 mg daily and some up-titrated to 1,600 mg/day for adequate control. Paediatric titration (ages 4 to 17) is weight-based, generally to a maintenance dose of 20 to 30 mg/kg/day capped at the adult range.

For epilepsy that responds, treatment is indefinite, with years of continuous use, periodic neurology review, sodium and LFT monitoring, and seizure-diary documentation.

Eligibility at a Saudi neurology clinic

For Saudi-resident patients, the neurology and epileptology services apply the FDA, EMA, and major-guideline criteria:

1. Confirmed diagnosis of partial-onset (focal) epilepsy by a neurologist or epileptologist, with EEG documentation of focal interictal or ictal discharges, MRI brain imaging, and a seizure history compatible with focal onset. 2. Age 4 or older for paediatric prescribing; renal function adjustment applies at any age. 3. Treatment history demonstrating either failure of an initial first-line antiepileptic, or a tolerability-driven need to move off carbamazepine or oxcarbazepine. 4. Baseline serum sodium and liver function tests. 5. Hormonal contraceptive review for women of reproductive potential. The CYP3A4 induction reduces combined oral contraceptive efficacy. 6. Pregnancy and lactation screen. Effective contraception is required during treatment. 7. Drug interaction screen for current medications. 8. Hepatic and renal function review. Severe hepatic impairment is a contraindication. 9. HLA screening in specific high-risk groups (HLA-A*3101 where clinically indicated).

A Saudi patient should arrive at the neurology conversation with EEG report, MRI brain report, complete seizure history, complete antiepileptic-drug history with response and tolerability data, baseline labs, and insurance card details (CCHI-registered cover; private insurance details). Reserve Meds organises this documentation pack so the neurology team can confirm eligibility on the first review.

The Saudi prescribing and dispense picture, plainly

Zebinix is SFDA-registered as the international brand for eslicarbazepine acetate. Aptiom-branded supply is rare in the kingdom and generally only relevant for a US-resident patient on a named-patient import. The functional supply chain is:

1. **Prescribing neurologist or epileptologist**: a board-certified Saudi neurologist with epilepsy experience, or a fellowship-trained epileptologist at a comprehensive epilepsy programme. The major Saudi centres are: - **Riyadh**: King Faisal Specialist Hospital and Research Centre Riyadh (the kingdom's flagship epilepsy programme with video-EEG, neurosurgical evaluation, and the full AED formulary), King Saud Medical City, Prince Sultan Military Medical City, King Khalid University Hospital, King Fahad Medical City, King Abdulaziz Medical City National Guard. - **Jeddah**: KFSHRC Jeddah neurology, International Medical Center Jeddah, Dr Sulaiman Al Habib network neurology. - **Dammam and Eastern Province**: King Fahad Specialist Hospital Dammam, Saudi Aramco Johns Hopkins Aramco Healthcare neurology. - **Paediatric**: King Saud Medical City paediatric neurology, KFSHRC paediatric neurology, King Fahad Medical City paediatric neurology, and the major private-sector paediatric services. 2. **Diagnostic workup**: EEG and MRI brain are run at the diagnosing centre. KFSHRC Riyadh and KFSHRC Jeddah have the deepest video-EEG and epilepsy surgery infrastructure in the kingdom and accept referrals from regional MoH and military hospitals for complex cases. 3. **Insurance pre-authorisation**: CCHI-regulated commercial insurance covers antiepileptic drugs as standard pharmacy benefit; the specialty-tier price band for Zebinix means some commercial insurers require a clinical rationale letter documenting prior AED failure or intolerance. NUPCO procurement supplies MoH and military hospital pharmacies; antiepileptic drugs on the SFDA-approved list are typically available through NUPCO with documented neurologist prescription. Pre-authorisation in commercial insurance typically takes 5 to 14 days for a complete file. 4. **Pharmacy dispense**: 30-day supply at the prescribing centre's outpatient pharmacy or partnered community pharmacy. Bial's MENA commercial distributor network handles Zebinix supply through Saudi distributors. 5. **Refill cycle**: monthly thereafter. Continued dispensing requires documentation of ongoing seizure-diary review and the periodic serum sodium monitoring described below.

The 2026 pathway, step by step

Week 0 to 2: Reserve Meds builds the documentation pack with the treating neurologist's office at KFSHRC, King Saud Medical City, Dr Sulaiman Al Habib, or another major Saudi neurology service. We collect EEG report, MRI brain report, complete seizure history, complete antiepileptic-drug history, baseline labs, and insurance documentation. The neurologist's office submits pre-authorisation if applicable.

Week 2 to 4: Insurance pre-authorisation review (where required). CCHI commercial covers typically turn this around within 1 to 3 weeks for antiepileptic drug coverage. For MoH or military-hospital patients, NUPCO supply is the standard channel and pre-authorisation is institutional.

Week 4 to 5: First dispense. Starting dose 400 mg once daily for the first week.

Week 5 to 6: Up-titration to 800 mg once daily. Most patients maintained at this dose.

Week 4 and month 3: Serum sodium checks documented and reviewed.

Month 3 to 6: Neurology follow-up to assess seizure-diary response, tolerability, and adherence. Dose adjustment if indicated.

Ongoing: Maintenance dosing once daily, monthly pharmacy refill, annual serum sodium check if stable, periodic LFT monitoring, continuous seizure diary review.

Cost expectation in SAR

US Aptiom list price (2026) is approximately USD 1,200 to USD 2,000 per 30-day supply at the maintenance dose tier, with annual cost approximately USD 14,000 to USD 24,000 per patient at list price. International Zebinix supply through the Saudi distributor channel generally lands at a lower price point.

At indicative 2026 cross rates, a 30-day Aptiom supply at USD 1,500 is approximately SAR 5,625, and the annual cost at USD 18,000 is approximately SAR 67,500. Zebinix supply through the Saudi channel typically lands in the SAR 3,750 to 5,625 monthly band, with annual cost in the SAR 40,000 to 67,500 band.

For Saudi nationals covered through MoH or military health services, Zebinix on the SFDA-approved AED list is typically available through NUPCO with documented neurologist prescription. CCHI-registered commercial covers vary; out-of-pocket exposure for a covered patient is generally a co-payment in the SAR 50 to 500 per month range, not the full list price. Cash-pay exposure depends on the dispensing pharmacy's regional pricing.

Monitoring on therapy

- **Serum sodium**: baseline, one month, three months, then annually if stable. More frequent for patients on diuretics, other hyponatraemia-associated medications, prior hyponatraemia history, or new symptoms. - **Liver function tests**: baseline and periodically. - **Seizure diary**: continuous patient-side documentation. - **Skin review**: immediate medical review for any new rash. Stevens-Johnson syndrome and toxic epidermal necrolysis are rare but reported with the dibenzazepine class. - **Alcohol caution**: counselling at first prescription. - **Driving caution**: Saudi driving regulations for patients with active epilepsy require a seizure-free interval before driving privileges are reinstated. The prescribing neurologist documents the driving-status conversation. - **Bone health**: long-term enzyme-inducing AED therapy is associated with reduced bone mineral density. Vitamin D supplementation and bone health monitoring appropriate for long-term therapy.

Religious, ethical, and family-logistics framing

Aptiom is an oral small molecule. No animal-source material in standard manufacturing, no donor cells, no biological product. Halal acceptability is not in question. The classical Islamic jurisprudential framework for chronic medication in serious illness endorses antiepileptic therapy.

The family-logistics burden of Aptiom sits in the chronicity, the adherence discipline, and the social context of an epilepsy diagnosis. Once-daily dosing is the operational advantage; one tablet at approximately the same time each day for years.

Epilepsy carries a heavier social stigma in some Saudi family contexts than in many Western settings, particularly for unmarried adolescent and young adult patients where the diagnosis can affect marriage prospects. The medical record is confidential and the diagnosis is shared only with the patient (and parents, for paediatric patients) at the patient's direction. Saudi neurology services handle this with discretion as standard practice.

For paediatric patients (ages 4 to 17), parental involvement in the medication-administration routine is standard. The once-daily schedule simplifies school-day logistics: the dose can be given at breakfast or bedtime depending on family preference.

For women of reproductive potential, the hormonal contraceptive interaction is a real conversation. CYP3A4 induction reduces combined oral contraceptive efficacy. Barrier or non-hormonal contraception is the standard recommendation. This conversation needs to happen before prescribing.

When Aptiom is not the right call

Aptiom is the right answer for confirmed partial-onset (focal) epilepsy in the indications above. It is not the right answer for primary generalised epilepsies (absence, juvenile myoclonic epilepsy, generalised tonic-clonic without focal onset), severe hyponatraemia history, Stevens-Johnson syndrome or toxic epidermal necrolysis history on a dibenzazepine, severe hepatic impairment (Child-Pugh C), pregnant women without specialist counsel, or patients with HLA-A*3101 positivity where clinically indicated.

Alternatives in 2026 are levetiracetam, lamotrigine, carbamazepine, oxcarbazepine, lacosamide, brivaracetam, perampanel, and surgical evaluation for medication-refractory cases. KFSHRC Riyadh and KFSHRC Jeddah run the surgical evaluation pathway.

Reserve Meds does not push a default. The page describes the Aptiom pathway because Aptiom is the antiepileptic the patient has asked about.

What Reserve Meds does on this case

We are a US-based concierge coordinator. We are not the prescriber and not the dispensing pharmacy. On a Saudi Aptiom case we build the documentation pack (EEG report, MRI brain report, complete seizure history, prior AED history, baseline labs), submit first-review requests to the chosen prescribing centre (KFSHRC, King Saud Medical City, Dr Sulaiman Al Habib, or another major centre), coordinate the insurance pre-authorisation conversation alongside the clinical workup, set up the first 30-day dispense at the chosen pharmacy, organise the baseline-plus-one-month-plus-three-month serum sodium monitoring schedule, and stay with the case through the first year of dosing with handoff to the local neurologist. Clinical decisions remain with your treating neurologist or epileptologist.

Reserve Meds's role

US-based concierge coordinator for cross-border specialty medicine. We are not the prescriber, not the dispensing pharmacy, and not the manufacturer. All clinical decisions remain with your treating physician.

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