Vumerity access in Jordan: the JFDA named-patient pathway

How Jordanian and regional patients pursue diroximel fumarate, an oral fumarate disease-modifying therapy for relapsing multiple sclerosis, with a more tolerable gastrointestinal profile than older fumarate options.

Last reviewed 2026-05-12 by Reserve Meds clinical and regulatory team. This page combines the Jordan country research module with the Vumerity drug module to describe the path families actually walk.

Quick orientation

Vumerity (diroximel fumarate) is an oral fumarate disease-modifying therapy for relapsing forms of multiple sclerosis, manufactured by Biogen. The drug was approved by the US Food and Drug Administration in October 2019 for relapsing forms of MS, including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults. Diroximel fumarate is a prodrug that is metabolised to monomethyl fumarate, the same active metabolite as dimethyl fumarate (Tecfidera), but the diroximel fumarate prodrug has been shown in head-to-head studies to produce fewer gastrointestinal adverse events. The standard dose is 231 mg orally twice daily for the first 7 days as a starter dose, then 462 mg orally twice daily as the maintenance dose, taken with or without food. Reserved for you.

Why this drug is hard to source in Jordan

Multiple sclerosis is well represented in Jordanian neurology practice, and the country has several MS disease-modifying therapies registered locally, including interferon-beta products, glatiramer acetate, oral therapies such as fingolimod, teriflunomide, and dimethyl fumarate, and infused therapies such as natalizumab and ocrelizumab. Vumerity, the newer diroximel fumarate prodrug, occupies a specific niche; it is the appropriate choice for a patient who has responded to fumarate disease-modifying therapy mechanistically but who has had to discontinue or reduce dimethyl fumarate because of gastrointestinal intolerance.

The drug is not consistently registered or stocked in Jordan. The combination of a smaller eligible patient population (specifically those needing fumarate therapy with the better GI profile), an older fumarate predecessor that is already on the market, and the manufacturer regional commercial footprint have left the named-patient pathway as the standard route.

Jordanian neurologists who identify Vumerity as the right next step file the JFDA permit; the medicine is imported in the patient name for dispensing at a JFDA-licensed facility.

The drug is registered in the US, EU, and several reference markets, so the JFDA recognition criterion is straightforwardly met. The application set is the standard one with neurology-specific elements.

The JFDA named-patient pathway

The Jordan Food and Drug Administration, headquartered in Amman, administers the personal-use and named-patient import permit under the Drug Directorate. The pathway allows hospitals, licensed pharmaceutical importers, and retail pharmacies operating under physician prescription to import a specific medicine for a specific patient when the medicine is approved by a recognised reference authority (US FDA, EMA, MHRA, Health Canada, TGA, PMDA) and a locally registered alternative is not suitable.

For a Vumerity case, the standard application set applies, with two additions specific to fumarate disease-modifying therapy. First, the clinical justification letter typically documents the MS diagnosis (relapsing-remitting MS, clinically isolated syndrome, or active secondary progressive MS), the disease activity history (relapse rate, MRI activity, Expanded Disability Status Scale where used), the prior disease-modifying therapy history with outcomes and reason for discontinuation, and the rationale for fumarate therapy with the better GI profile. Where the patient has had to discontinue dimethyl fumarate (Tecfidera) for gastrointestinal intolerance, the documentation of that intolerance is a key element. Second, the application typically captures the baseline complete blood count and the plan for periodic lymphocyte monitoring, as fumarate therapy carries the warning for progressive multifocal leukoencephalopathy and the lymphocyte count monitoring is part of the responsible prescribing plan.

A complete JFDA application typically includes the clinical justification letter from the treating neurologist, the neurologist JPA membership and MOH registration verification, the patient identifier, full product details (brand name Vumerity, generic name diroximel fumarate, manufacturer Biogen, 231 mg delayed-release capsule, pack size, quantity, intended treatment duration), the destination dispensing facility name and JFDA pharmaceutical establishment license number, the MS diagnostic documentation, and a chain-of-custody plan. Vumerity capsules are stored at room temperature (20 to 25 degrees Celsius), so cold-chain is not required. Approval timelines run 7 to 21 calendar days from a complete submission.

Real costs in JOD and USD

The US wholesale acquisition cost for Vumerity is approximately USD 7,500 to 8,500 per 30-day supply at the standard maintenance dose of 462 mg twice daily. In JOD at the 0.71 peg, this is approximately JOD 5,325 to 6,035 per month. Annual cost at maintenance is approximately USD 90,000 to 102,000 (approximately JOD 64,000 to 72,500).

International logistics for a room-temperature oral therapy into Jordan typically runs USD 400 to 800 (approximately JOD 285 to 570). JFDA permit fees and Jordan Customs handling are nominal relative to the drug cost. Regulatory documentation handling and the Reserve Meds concierge fee are itemised separately on every firm quote.

On the insurance side, RMS and MOH schemes cover MS disease-modifying therapy for their beneficiaries case by case, often with a preference for locally registered therapies first and named-patient imports where clinical justification supports the specific molecule. Private insurers (MetLife, Generali, Arab Orient, Jordan Insurance, Mediterranean and Gulf) assess named-patient MS therapy individually and most require pre-authorisation. The Vumerity case typically benefits from documentation that the patient has tried, and discontinued for intolerance, the locally registered fumarate alternative. Reserve Meds supplies the documentation set that lets your insurer assess the case. We do not promise coverage from any insurer.

Timing, what to expect

The JFDA permit itself processes in approximately 7 to 21 calendar days from a complete submission. The full timeline from the first physician contact to the patient receiving the first dose is typically 3 to 6 weeks for a Vumerity case. The treating neurologist clinical justification letter and prior-therapy intolerance documentation assembly typically takes a few days to one week. The JFDA application filing and approval window runs 7 to 21 calendar days. US-side sourcing and shipment scheduling, in parallel with the JFDA review, takes 3 to 7 business days. Customs clearance at Queen Alia International Airport and delivery to the dispensing pharmacy typically takes 1 to 3 business days post-shipment.

The dose schedule is 231 mg orally twice daily for the first 7 days (one capsule twice daily, the starter dose), then 462 mg orally twice daily as the maintenance dose (two capsules twice daily). Treatment is open-ended; the patient continues as long as the drug provides clinical benefit and tolerability is maintained.

What your physician needs

The clinical justification letter for a Vumerity JFDA submission is the cornerstone of the application. The treating neurologist letter typically addresses the patient MS diagnosis

(relapsing-remitting MS, CIS, or active secondary progressive MS with the basis for the diagnosis documented), the disease activity history (relapse rate, MRI activity, EDSS), the prior disease-modifying therapy history with outcomes and reason for discontinuation, the prior fumarate therapy history specifically where applicable (dimethyl fumarate response and gastrointestinal intolerance, where the patient is moving from Tecfidera to Vumerity), and the planned monitoring plan (complete blood count with differential at baseline and then periodically, attention to lymphocyte count for PML risk, liver function tests, awareness of flushing and gastrointestinal effects).

The treating neurologist JPA membership and MOH registration must be in active standing. The destination dispensing facility must hold a JFDA pharmaceutical establishment license. The MS diagnostic documentation (clinical history, MRI findings, McDonald criteria assessment) must be in the patient record. The patient identifier is included on the application.

King Hussein Cancer Center and the Jordan specialty-dispensing network

Vumerity for relapsing multiple sclerosis is not a King Hussein Cancer Center case; KHCC mandate is oncology and hematology. For MS disease-modifying therapy, the natural Jordanian dispensing institutions are the academic teaching hospitals and the larger private specialty hospitals with neurology service lines.

Jordan University Hospital in Amman, with its established neurology service line and its MS clinic, is a natural Amman-area dispensing institution. King Abdullah University Hospital in Irbid, with its neurology service line, serves northern Jordan. Istishari Hospital, Specialty Hospital, and Arab Medical Center on the private side each have neurology service lines and either operate in-house import pharmacies or route through an Amman-based specialty pharmaceutical importer. Royal Medical Services hospitals serve military and security beneficiaries with their own MS programs.

For neurologists at smaller hospitals or private clinics without internal import infrastructure, the standard pattern is to route through an Amman-based specialty pharmaceutical importer that holds the JFDA establishment license, files the permit on the prescribing physician behalf, performs customs clearance at Queen Alia International Airport, and delivers the medicine to the prescribing physician pharmacy under chain-of-custody documentation.

Pharmacovigilance and cold-chain

Vumerity capsules are stored at room temperature (20 to 25 degrees Celsius) with permitted excursions to 15 to 30 degrees Celsius. Cold-chain transport is not required. The

shipping packet captures temperature trace from US release through Jordanian dispensing for quality assurance.

Jordan operates a national pharmacovigilance system administered by the JFDA Drug Directorate, and is a member of the WHO Programme for International Drug Monitoring through the Uppsala Monitoring Centre. The treating neurologist and the dispensing facility share the duty to report adverse drug reactions through the JFDA portal at jfda.jo. The Vumerity safety profile includes flushing (manageable with dose timing and aspirin prophylaxis where appropriate), gastrointestinal effects (substantially less common than with dimethyl fumarate), lymphopenia (requires periodic complete blood count monitoring), the rare risk of progressive multifocal leukoencephalopathy associated with prolonged severe lymphopenia (boxed concern across the fumarate class), liver injury, and hypersensitivity reactions. Serious adverse reactions are reported within 15 calendar days; other significant adverse events fall within 30-day or 90-day windows depending on severity.

Common questions about Vumerity in Jordan

Will RMS, MOH, or private insurers cover Vumerity when Tecfidera is on the local register? Coverage typically requires documentation that the patient has tried the locally registered fumarate option (dimethyl fumarate, Tecfidera) and has had to discontinue or reduce it for gastrointestinal intolerance. Where that documentation is in hand, the named-patient case for Vumerity is much stronger. We supply the documentation set that lets your insurer assess the case.

Is MS specialty care available in Jordan? Yes. JUH, KAUH, and several private specialty hospitals run MS clinics with neurologists experienced in disease-modifying therapy selection. The Jordan Society of Neurology is active in continuing education for MS management.

Can I switch from Tecfidera to Vumerity? Yes, and that is the most common Vumerity case in markets where Vumerity is not first-line. The transition is typically direct, with the patient discontinuing dimethyl fumarate and starting diroximel fumarate at the starter dose. The clinical decision and the transition plan rest with the treating neurologist.

What about the PML risk? The fumarate class carries a documented but rare risk of progressive multifocal leukoencephalopathy, particularly in patients with prolonged severe lymphopenia. Periodic complete blood count monitoring with attention to lymphocyte count is the standard responsible prescribing practice across the class.

Is Vumerity a controlled substance? No. Vumerity is not a DEA scheduled substance. The Anti-Narcotics Department coordination does not apply.

Where Reserve Meds fits in Vumerity cases

Reserve Meds is a US-based concierge coordinator. We do not replace your treating neurologist, the JFDA, the dispensing pharmacy, or the receiving institution. For a Vumerity case, our work is treating-physician coordination on the documentation kit, US-side sourcing of the manufacturer or authorised distributor product, ambient shipment to the Jordanian importer or hospital pharmacy of record, and a single named coordinator through the case. The clinical decisions, the JFDA filing, and the dispensing all sit with your Jordanian neurologist and the dispensing facility. Reserved for you.

Next step

If a treating neurologist in Jordan is weighing Vumerity for a patient with relapsing MS, particularly one who has had to discontinue dimethyl fumarate for GI intolerance, the waitlist is the first step. We respond within 24 to 48 hours with an eligibility confirmation and a documentation kit for the physician.

Reserved for you.

Related

- Vumerity clinical resource
- Vumerity in Saudi Arabia
- Vumerity in the UAE
- Tecfidera in Jordan
- Jordan country page
- Multiple sclerosis condition page

Sources

1. FDA approval, Vumerity (diroximel fumarate), Biogen, NDA approval October 2019 for relapsing forms of multiple sclerosis.
2. Jordan Food and Drug Administration, jfda.jo, Drug Directorate framework for personal-use and named-patient import permits; Law No. 41 of 2008.
3. Central Bank of Jordan, fixed exchange rate framework, JOD-USD peg at approximately 0.71 JOD per USD since 1995.
4. EVOLVE-MS-2 head-to-head gastrointestinal tolerability study, diroximel fumarate versus dimethyl fumarate.

Review and oversight. Content on this page is reviewed by the Reserve Meds 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 ›

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