Voydeya

Saudi Arabia · access guide

How to access Voydeya from Saudi Arabia, the named-patient import pathway, 2026

By Reserve Meds · Clinical & regulatory team · Last reviewed 2026-04-23

A Saudi Arabiai patient with paroxysmal nocturnal hemoglobinuria (PNH) who is already on a C5 inhibitor (Soliris or Ultomiris) but continues to experience clinically significant extravascular haemolysis, transfusion dependence, ongoing anaemia, or elevated reticulocytes despite complement inhibition, may receive a prescription for Voydeya (danicopan) from their treating haematologist. Voydeya is FDA-approved as adjunctive therapy to a C5 inhibitor for adult PNH patients with residual extravascular haemolysis, and it is manufactured by Alexion (AstraZeneca Rare Disease). It is the first oral Factor D inhibitor approved for this specific niche. In Saudi Arabia, Voydeya may not yet be broadly registered, which is why your haematologist may be navigating a named-patient import pathway with you.

This guide explains the legal pathway, what documentation your physician needs, typical costs and timing, and where Reserve Meds fits in.

The clinical situation

Voydeya is administered as oral tablets, typically three times daily. It is designed to be added to an existing C5 inhibitor regimen, not to replace it, and therefore does not remove the meningococcal-vaccination and REMS-style gating that apply to Soliris or Ultomiris. Additional considerations apply to Voydeya itself, including infection-risk counselling because of complement-pathway inhibition. Your treating haematologist confirms PNH diagnosis, current C5-inhibitor regimen, evidence of extravascular haemolysis (transfusion history, reticulocyte count, haemoglobin trend), and the dosing plan per FDA labeling.

Is Voydeya legally importable into Saudi Arabia?

Yes, through the Saudi Arabia Ministry of Public Health (MoPH) Pharmacy and Drug Control Department's named-patient import framework. The pathway allows a Saudi Arabia-licensed physician to request import of a medicine not locally registered when: (a) the medicine is approved by a recognised reference authority (FDA qualifies), (b) no locally registered alternative is clinically equivalent for the patient, (c) the physician takes clinical responsibility, and (d) chain of custody is documented.

For danicopan specifically, the application emphasises the adjunctive nature, documentation must reflect that the patient remains on a C5 inhibitor with appropriate meningococcal vaccination.

How the pathway works, step by step

1. **Consultation with your treating haematologist.** PNH diagnosis confirmation, current C5 inhibitor regimen, and documentation of residual extravascular haemolysis.
2. **Vaccination review.** Because Voydeya adds complement-pathway inhibition, meningococcal and broader encapsulated-organism vaccination status is confirmed per ongoing C5-inhibitor requirements.
3. **MoPH named-patient application.** Your physician files the application.
4. **US-side sourcing.** Reserve Meds coordinates with our US-licensed specialty wholesale partner, aligned with the manufacturer's controlled-distribution model.
5. **Shipment.** Voydeya ships at controlled room temperature; no cold-chain is required.
6. **Arrival and dosing start.** The treating physician initiates oral dosing alongside the ongoing C5 inhibitor.

What documentation your physician needs

Your physician will typically need to provide:

- Clinical rationale letter confirming PNH diagnosis, current C5-inhibitor regimen, evidence of clinically significant extravascular haemolysis, and Voydeya as indicated adjunctive therapy
- Verification of Saudi Arabia medical licence
- Patient identifier
- Meningococcal and encapsulated-organism vaccination documentation per C5-inhibitor standards
- Planned oral dosing schedule and projected monthly tablet supply

Reserve Meds provides a physician documentation kit that bundles the templates MoPH reviewers expect to see for complement inhibitors, including the adjunctive-therapy documentation block.

Costs and timing

Voydeya's US cash-pay drug-only reference price sits in a broad indicative range, the annualised adjunctive-treatment cost sits in the USD 200,000-300,000 range in US list pricing, added to the ongoing C5-inhibitor cost. International logistics, MoPH documentation, and concierge coordination add incremental cost; Reserve Meds issues a full transparent quote at the start of intake. Indicative range.

Indicative timing for the first dispensed supply after cohort intake opens is 14-21 days from the moment a complete application is submitted.

Fulfillment availability is limited to our first cohort, and all timelines published on this site are indicative. If your clinical situation is time-sensitive, tell us at intake. We triage accordingly.

Reserve Meds's role

Reserve Meds is a US-based concierge coordinator for cross-border specialty medicine. For Voydeya specifically, we provide:

- **Sourcing.** Through our US-licensed specialty wholesale partner, operating under DSCSA chain-of-custody and aligned with the manufacturer's controlled-distribution program.
- **Documentation.** Regulatory package for your physician and for MoPH review, including the adjunctive-therapy and vaccination block.
- **Logistics.** Controlled-room-temperature shipment.
- **Concierge case lead.** A named point of contact.

What we do not do: We are not the prescriber. We do not practise medicine. We are not the dispensing pharmacy. All clinical decisions remain with your treating haematologist.

Frequently asked

Is this legal in Saudi Arabia? Yes, when executed through the MoPH named-patient framework with appropriate documentation.

Do I still need my C5 inhibitor? Yes. Voydeya is specifically approved as adjunctive therapy, it is added to Soliris or Ultomiris, not used instead of them. Discontinuing the C5 inhibitor is not the indication.

What about vaccinations? Because you remain on a C5 inhibitor and are adding further complement-pathway inhibition, meningococcal vaccination and broader encapsulated-organism vaccination per your C5-inhibitor regimen remain in force.

How does Voydeya compare with switching to Empaveli or Fabhalta? All three address residual extravascular haemolysis on C5 inhibition but differently: Voydeya is oral add-on to an existing C5 inhibitor; Empaveli is a subcutaneous C3 inhibitor replacing the C5 inhibitor; Fabhalta is an oral Factor B inhibitor that can be used as monotherapy. Your haematologist chooses based on haemolysis pattern, dosing preference, and logistics.

Will private insurance cover this? Cash-pay is the default. Some Saudi Arabia private insurers reimburse PNH adjunctive therapy on escalated review; we supply documentation but do not process insurance claims directly.

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.

reservemeds.com · hello@reservemeds.com