Darzalex

Saudi Arabia · access guide

How to access Darzalex or Darzalex Faspro for multiple myeloma or AL amyloidosis from Saudi Arabia: 2026 pathway via KFSHRC, KAMC, KFMC, PSMMC and the wider kingdom haematology network

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

Darzalex (daratumumab) and Darzalex Faspro (daratumumab plus hyaluronidase-fihj) are both registered with the Saudi Food and Drug Authority and form the foundation of multiple myeloma care across the Kingdom. KFSHRC Riyadh runs the deepest adult haematology and BMT programme in the Gulf, with more than 200 commercial CAR-T patients treated since 2020 and an in-house point-of-care CD19 CAR-T manufacturing facility opened in late 2025. KAMC Riyadh and Jeddah (National Guard Health Affairs), KFMC Riyadh, Prince Sultan Military Medical City (PSMMC), Princess Noorah Oncology Center (PNOC) Jeddah, KFSHRC Jeddah, Specialised Medical Center Hospital Riyadh, and the Dr Suliman Al Habib hospital network complete the kingdom myeloma infrastructure. For a Saudi-resident adult newly diagnosed with multiple myeloma in 2026, daratumumab in combination is the standard induction conversation. The operational question for most patients is which combination, which formulation (IV or SC), where in the kingdom to receive the loading schedule, and how the year-on-year monthly maintenance fits with work and family logistics.

This page explains how the pathway works in 2026 for a Saudi-resident adult: who qualifies, which kingdom centres administer routinely, what the schedule looks like across induction-consolidation-maintenance, what realistic cost looks like in SAR under MoH and National Guard funding, what infusion-reaction and HBV-screening preparation is needed, and what to do about the cross-match interference that Darzalex causes for the duration of treatment.

Why Darzalex Faspro, and why now

Daratumumab is a humanised IgG1 kappa monoclonal antibody developed by Genmab and commercialised by Johnson & Johnson Innovative Medicine (Janssen Biotech). It targets CD38, a protein highly expressed on multiple myeloma cells and on the clonal plasma cells of AL amyloidosis. The mechanism is multi-pronged: complement-dependent cytotoxicity, antibody-dependent cellular cytotoxicity and phagocytosis, direct apoptosis induction, immunomodulation through depletion of CD38-positive regulatory T cells and myeloid-derived suppressor cells, and inhibition of CD38 ectoenzymatic activity.

Darzalex IV was FDA approved in November 2015. Darzalex Faspro, the SC co-formulation with recombinant human hyaluronidase, was FDA approved in May 2020 and has equivalent efficacy with a substantially lower infusion-reaction rate (approximately 10 percent vs approximately 50 percent for first IV infusion) and a 5-minute injection time versus a 7-hour first IV infusion (COLUMBA Phase 3). The PERSEUS Phase 3 trial (NEJM 2024) established Darzalex Faspro plus VRd (D-VRd) as the preferred quadruplet induction-consolidation-maintenance regimen for transplant-eligible newly diagnosed MM, with 48-month progression-free survival 84.3 percent vs 67.7 percent for VRd alone. FDA approved D-VRd for transplant-eligible NDMM in July 2024.

For a Saudi patient newly diagnosed with multiple myeloma, the treating haematologist's induction conversation in 2026 typically centres on D-VRd quadruplet for transplant-eligible patients (the KFSHRC, KAMC, KFMC, and PSMMC standard) or D-Rd (MAIA regimen) for transplant-ineligible patients. For relapsed or refractory disease the conversation moves to D-Vd, D-Kd, D-Pd, or to a BCMA bispecific T-cell engager or BCMA CAR-T depending on prior exposure profile.

What Darzalex Faspro is, in plain language

The drug is injected under the skin of the abdomen. A single 1800 mg fixed dose, co-formulated with hyaluronidase-fihj (a recombinant enzyme that temporarily breaks down the connective tissue under the skin to allow rapid absorption of the volume), is delivered over 3 to 5 minutes. There is no infusion line, no central venous access requirement, and no multi-hour chair time. Observation for 6 hours after the first dose for delayed reactions; observation shortens to 30 to 60 minutes with subsequent doses.

The schedule: weekly weeks 1 through 8 (8 doses); every two weeks weeks 9 through 24 (8 doses); every four weeks from week 25 onwards until disease progression, intolerable toxicity, or end of planned treatment course.

Premedications before each dose: oral or IV corticosteroid (dexamethasone or methylprednisolone), antihistamine (diphenhydramine), antipyretic (acetaminophen / paracetamol). Montelukast 10 mg orally for the first dose, optional thereafter. Post-treatment oral corticosteroids for the two days after the first dose to reduce delayed reaction risk.

Eligibility at a Saudi haematologist or medical oncologist clinic

For Saudi-resident patients, daratumumab eligibility is broad. The clinical conversation is about which combination at which line.

1. Confirmed multiple myeloma per IMWG criteria, or confirmed AL amyloidosis with tissue biopsy demonstrating amyloid deposits plus underlying plasma cell dyscrasia. 2. Adequate cardiac function: baseline ECHO with LVEF, particularly important for AL amyloidosis and for carfilzomib-containing regimens. 3. For combinations with lenalidomide: creatinine clearance and tolerance assessment. 4. For combinations with bortezomib: baseline neuropathy assessment. 5. Hepatitis B virus screening (HBsAg, anti-HBc) before initiation. HBV reactivation has been reported. HBV-positive patients require antiviral prophylaxis (entecavir or tenofovir) and HBV DNA monitoring throughout treatment. 6. Baseline CBC with differential, comprehensive metabolic panel, immunoglobulin levels, serum free light chains, SPEP and UPEP with immunofixation. 7. Type and screen the patient and notify the blood bank: daratumumab interferes with indirect Coombs and cross-match testing for up to 6 months after the last dose because CD38 is expressed on reagent red blood cells. The patient receives a Darzalex patient ID card; the blood bank uses dithiothreitol (DTT)-treated red cells for cross-matching after initiation. 8. Pregnancy testing in women of reproductive potential; effective contraception during and for three months after the last dose. 9. Vaccination review: avoid live vaccines; consider pneumococcal, influenza, and recombinant zoster vaccines before initiation where feasible.

A Saudi patient should arrive with the most recent diagnostic workup: SPEP and UPEP with immunofixation, serum free light chain assay, bone marrow biopsy and aspirate with cytogenetics including FISH for del17p, t(4;14), t(14;16), gain 1q, whole-body MRI or low-dose whole-body CT, PET-CT where the centre uses it, beta-2-microglobulin, albumin, LDH, treatment history. For AL amyloidosis: cardiac biomarkers (NT-proBNP, troponin), 24-hour urine protein, cardiac MRI or ECHO with strain imaging, involved-organ assessment.

The Saudi administration picture, plainly

Darzalex Faspro is administered routinely across the kingdom adult haematology and medical oncology network:

- **King Faisal Specialist Hospital and Research Centre (KFSHRC), Riyadh**: the deepest adult haematology and BMT programme in the Gulf; daratumumab combination induction and maintenance are standard practice; in-house point-of-care CD19 CAR-T manufacturing facility opened late 2025 (academic CAR-T, distinct operational track from commercial CAR-T pricing). - **KFSHRC Jeddah**: secondary KFSHRC site. - **King Abdulaziz Medical City (KAMC), Riyadh and Jeddah**: National Guard Health Affairs adult haematology and BMT programmes; daratumumab is part of the NGHA standard MM induction protocol. - **King Fahad Medical City (KFMC), Riyadh**: adult haematology and lymphoma referral. - **Prince Sultan Military Medical City (PSMMC), Riyadh**: adult haematology and oncology; military health services coverage. - **Princess Noorah Oncology Center (PNOC), Jeddah**: adult oncology and haematology. - **Specialised Medical Center Hospital, Riyadh**: adult oncology. - **Dr Suliman Al Habib hospitals**: adult oncology and haematology across the kingdom.

The Saudi Food and Drug Authority is the regulator. Janssen Saudi Arabia coordinates supply. Both Darzalex IV and Darzalex Faspro are widely available; the SC formulation is the operational default for adult MM since 2021.

The 2026 pathway, step by step

Week 0 to 2: Diagnostic workup and treatment-plan discussion with the treating haematologist or medical oncologist. Reserve Meds assembles the document pack where it helps the family understand the regimen choice; the clinical decision sits with the treating physician.

Week 2 to 3: HBV screening, blood bank type-and-screen and DTT cross-match protocol setup, baseline cardiac assessment if carfilzomib or AL amyloidosis is in the picture, baseline labs, treatment-plan finalisation.

Week 3: First dose. Darzalex Faspro SC: premedications, single 1800 mg fixed dose SC injection over 3 to 5 minutes, 6-hour post-dose observation, post-treatment oral corticosteroid for two days. Darzalex IV: 7-hour first infusion with split-dose option.

Weeks 4 to 11: Weekly doses. Each subsequent dose tolerated more easily; observation period shortens.

Weeks 12 to 24: Every-two-week doses.

Week 25 onwards: Every-four-week dosing for the duration of the treatment plan. For D-VRd transplant-eligible NDMM the schedule continues through induction, consolidation, transplant, and maintenance. For D-Rd transplant-ineligible NDMM the schedule continues until progression.

Ongoing: CBC with differential before each dose; SPEP and serum free light chains each cycle; comprehensive metabolic panel; periodic immunoglobulin levels; infection surveillance.

Cost expectation in SAR

Darzalex Faspro Saudi pricing per 1800 mg single-dose vial typically runs SAR 28,000 to 34,000 (subject to confirmation at intake; MoH tender and payer pricing vary by purchaser). A standard induction-through-month-12 schedule (8 weekly plus 8 every-two-week plus monthly maintenance through year 1) uses 24 to 26 doses, costing approximately SAR 700K to 880K for daratumumab alone. After year 1, monthly maintenance costs approximately SAR 350K to 430K per year for daratumumab alone.

Combination regimen costs add lenalidomide (Revlimid or generic), bortezomib (Velcade or generic), or pomalidomide on top. D-Rd in transplant-ineligible NDMM adds lenalidomide approximately SAR 200K to 350K per year. D-VRd in transplant-eligible NDMM adds both bortezomib and lenalidomide during induction.

For Saudi nationals, MoH and National Guard Health Affairs and PSMMC military coverage routinely cover daratumumab combinations as standard-of-care induction and maintenance. KFSHRC, KAMC, KFMC, and PSMMC patients on the national tender receive daratumumab through their respective sector budgets. For expatriate residents, employer-sponsored insurance covers daratumumab for the registered indications subject to pre-authorisation; cash-pay-with-documentation patterns apply where insurance has annual ceiling caps.

Religious, ethical, and family-logistics framing

Daratumumab is a recombinant monoclonal antibody manufactured in mammalian cell culture (Chinese hamster ovary cells). The hyaluronidase-fihj component of Darzalex Faspro is recombinant human hyaluronidase, also manufactured in CHO cells. No porcine, bovine, or human-derived component is used in the final product. The injection or infusion is permissible across Saudi Islamic jurisprudence on the same footing as other recombinant biologic therapies.

Multiple myeloma is overwhelmingly an adult disease, median age at diagnosis 65 to 70 years. The treatment-plan conversation involves the patient and adult children or spouse; weekly then every-other-week then monthly visits over years require family transport coordination, especially for elderly patients.

HBV screening before initiation is a hard rule. Saudi-resident expatriates from higher-prevalence regions need explicit screening at first daratumumab discussion.

Cross-match interference is the operational fact that families often miss. The patient must carry a Darzalex patient ID card. Before any planned transfusion, the blood bank must be notified that the patient is on daratumumab; DTT-treated red cells are used for cross-matching. The interference persists for up to 6 months after the last dose.

When Darzalex Faspro is not the right call

For a Saudi patient with confirmed daratumumab refractoriness (progression on or within 60 days of a daratumumab-containing regimen), the operational alternative is isatuximab (Sarclisa, Sanofi), the other commercial anti-CD38 monoclonal antibody with a different binding epitope. For triple-class-exposed relapsed-refractory disease (refractory to IMiD, PI, and anti-CD38 mAb), the operational pathway moves to BCMA bispecifics (teclistamab, elranatamab), to GPRC5D-directed talquetamab, or to BCMA CAR-T (Abecma or Carvykti, with KFSHRC Riyadh as the regional reference centre for CAR-T administration). For patients with active HBV without adequate antiviral coverage, daratumumab initiation is deferred. For patients with grade 3+ infusion reaction to first IV dose, SC formulation may be tolerated; persistent grade 3+ across both formulations requires discontinuation.

For AL amyloidosis with advanced cardiac staging (Mayo Stage IIIb), initiation is more delicate; D-VCd is still the standard first-line but timing and supportive cardiac coordination are critical.

Reserve Meds does not push a default regimen. The page above describes the Darzalex Faspro pathway because daratumumab is the backbone biologic the patient has asked about. If the conversation with the treating haematologist points toward isatuximab, a bispecific, CAR-T, or a non-CD38 regimen, the operational pathway shifts accordingly and we coordinate that pathway instead.

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 Darzalex or Darzalex Faspro case we build the document pack, coordinate pre-treatment HBV screening logistics and blood bank notification, support pre-authorisation conversations with MoH or NGHA or PSMMC or commercial insurers, coordinate supply continuity where the patient is on a longer maintenance schedule, and stay with the case through the induction-consolidation-maintenance arc. Clinical decisions remain with your treating haematologist or medical oncologist.

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.

Reserve Meds

reserved for you.

Composite case examples. This document is for general information only and does not constitute medical advice. Please consult your treating physician.
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