

## Darzalex

United Arab Emirates · access guide

# How to access Darzalex or Darzalex Faspro for multiple myeloma or AL amyloidosis from the UAE: 2026 pathway via UAE haematology and oncology centres

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

Darzalex (daratumumab) is now a foundational component of multiple myeloma care in the UAE. Both the intravenous formulation (Darzalex IV) and the subcutaneous formulation (Darzalex Faspro, daratumumab with hyaluronidase-fihj) are registered with the Emirates Drug Establishment, and both are administered routinely across the UAE adult haematology and medical oncology network. For a UAE-resident adult newly diagnosed with multiple myeloma in 2026, daratumumab is part of the standard induction conversation, not a salvage option. The operational question for most patients is which combination, which formulation, where to receive the loading schedule, and how the year-on-year monthly maintenance fits with work, travel, and family logistics. This page covers Darzalex Faspro because the subcutaneous formulation has largely displaced the IV formulation for adult MM since 2020 (5-minute injection versus 7-hour first IV infusion), with reference to Darzalex IV where the centre uses IV specifically.

This page explains how the pathway works in 2026 for a UAE-resident adult: who qualifies, which centres administer routinely, what the schedule looks like across induction and maintenance, what realistic cost looks like in AED, 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, antibody-dependent cellular 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 subcutaneous 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. The COLUMBA Phase 3 trial established non-inferiority of SC vs IV.

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 a 48-month progression-free survival of 84.3 percent versus 67.7 percent for VRd alone. The FDA approved D-VRd for transplant-eligible NDMM in July 2024.

For a UAE patient newly diagnosed with multiple myeloma in 2026, the treating haematologist's induction conversation will typically centre on D-VRd quadruplet for transplant-eligible patients 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

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The drug is injected under the skin of the abdomen. A single 1800 mg fixed dose, co-formulated with hyaluronidase-fihj (an 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. The patient is observed for 6 hours after the first dose for delayed reactions; observation shortens with subsequent doses to a standard 30 to 60 minutes.

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

For D-VRd transplant-eligible NDMM, the daratumumab continues through induction, consolidation, and maintenance phases. For D-Rd in transplant-ineligible NDMM, daratumumab continues until progression. For relapsed-refractory combinations, schedule depends on the partner regimen.

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

## Eligibility at a UAE haematologist or medical oncologist clinic

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For UAE-resident patients, daratumumab eligibility is broad. The clinical conversation is about which combination at which line, not whether daratumumab itself applies.

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: ECHO with left ventricular ejection fraction; baseline cardiac assessment is particularly important for AL amyloidosis cases 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, serum protein electrophoresis with immunofixation, urine protein electrophoresis. 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 to carry. 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 UAE patient should arrive at the daratumumab conversation with the most recent diagnostic workup in hand: SPEP and UPEP with immunofixation, serum free light chain assay, bone marrow biopsy and aspirate with cytogenetics including FISH for high-risk markers (del17p, t(4;14), t(14;16), gain 1q), whole-body MRI or skeletal survey or low-dose whole-body CT, PET-CT where the centre uses it, beta-2-microglobulin, albumin, LDH, and a current treatment history. For AL amyloidosis: cardiac biomarkers (NT-proBNP, troponin), 24-hour urine protein, cardiac MRI or ECHO with strain imaging, and the involved-organ assessment.

## The UAE administration picture, plainly

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Darzalex Faspro is administered routinely across the UAE adult haematology and medical oncology network. The centres include:

- **Cleveland Clinic Abu Dhabi**, with an established adult haematology, BMT, and medical oncology service. - **Sheikh Shakhbout Medical City**, with MD Anderson Cancer Center affiliation and an active adult haematology service. - **Tawam Hospital, Al Ain**, the federal oncology centre of excellence, with deep adult oncology and haematology infrastructure. - **Burjeel Medical City, Abu Dhabi**, with an adult oncology and BMT programme. - **Mediclinic City Hospital, Dubai**, with an active adult medical oncology and haematology service. - **American Hospital Dubai**, with adult oncology and haematology. - **King's College Hospital London Dubai**, with adult haematology and oncology. - **Saudi German Hospital Dubai**, with an adult oncology service. - **Mediclinic Parkview, Dubai**, with adult oncology. - **NMC Royal Hospital Khalifa City**, with adult oncology. - **Aster Hospitals**, with adult oncology services across multiple emirates.

The Emirates Drug Establishment is the federal regulator. Janssen Middle East holds the marketing authorisation and coordinates supply. Both Darzalex IV and Darzalex Faspro are widely available; the SC formulation is the operational default for adult MM since 2021.

For UAE-resident adults seeking BMT or BCMA CAR-T as the next operational step after daratumumab-containing induction or salvage, the cross-emirate or cross-border referral is to Cleveland Clinic Abu Dhabi, Sheikh Shakhbout Medical City, or KFSHRC Riyadh.

## The 2026 pathway, step by step

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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, and treatment-plan finalisation.

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

Weeks 4 to 11: Weekly doses (8 total in weeks 1-8 of treatment). Each subsequent dose tolerated more easily; observation period shortens.

Weeks 12 to 24: Every-two-week doses (8 total in weeks 9-24).

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; serum protein electrophoresis and serum free light chains each cycle; comprehensive metabolic panel; periodic immunoglobulin levels; infection surveillance with low threshold for early antimicrobial intervention.

## Cost expectation in AED

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Darzalex Faspro UAE pricing per 1800 mg single-dose vial typically runs AED 28,000 to 35,000 (subject to confirmation at intake; tender and payer pricing vary). A standard induction-through-month-12 schedule (8 weekly plus 8 every-two-week plus monthly maintenance through the first year) uses 24 to 26 doses, costing approximately AED 700K to 900K for daratumumab alone over the first year. After year 1, monthly maintenance dosing costs approximately AED 350K to 450K per year for daratumumab alone.

Combination regimen costs add lenalidomide (Revlimid, BMS), bortezomib (Velcade, Takeda or Bortenat generic), or pomalidomide (Pomalyst, BMS) on top. D-Rd in transplant-ineligible NDMM is daratumumab plus lenalidomide plus dexamethasone; lenalidomide UAE pricing adds approximately AED 200K to 350K per year depending on dose. D-VRd in transplant-eligible NDMM adds both bortezomib and lenalidomide during induction.

For Emirati nationals, Thiqa coverage for SFDA-registered or EDE-registered standard-of-care oncology regimens has historically extended to daratumumab combinations on the standard tender. The pre-authorisation conversation needs to happen at induction planning rather than mid-regimen. For UAE residents with employer-sponsored Daman or commercial cover, daratumumab is typically covered for the registered indications subject to pre-authorisation; ceiling caps on annual oncology benefit can apply for high-tier plans. For expatriates without local insurance, self-pay is the path; payment plans through the dispensing pharmacy are sometimes available for the longer-tail maintenance phase.

## **Religious, ethical, and family-logistics framing**

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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 MENA Islamic jurisprudence on the same footing as other recombinant biologic therapies (insulin analogues, monoclonal antibodies for rheumatology, oncology biosimilars, etc.).

Multiple myeloma is overwhelmingly an adult disease, with median age at diagnosis 65 to 70 years. The treatment-plan conversation involves the patient and adult children or spouse; the operational rhythm of weekly then every-other-week then monthly visits over years requires family transport coordination, especially for elderly patients who may not drive themselves.

The HBV screening conversation needs to happen at first daratumumab discussion. MENA HBV prevalence varies; UAE-resident expatriates from higher-prevalence regions need explicit screening before initiation.

Cross-match interference is the operational fact that families often miss. The patient must carry a Darzalex patient ID card. Before any planned transfusion (during salvage chemotherapy, surgery, or the BMT phase), 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**

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For a UAE patient with confirmed daratumumab refractoriness (defined as 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; sequential CD38-directed therapy after daratumumab refractoriness is sometimes effective. For triple-class-exposed relapsed-refractory disease (refractory to IMiD, PI, and anti-CD38 mAb), the operational pathway moves to BCMA bispecific T-cell engagers (teclistamab, elranatamab), to GPRC5D-directed talquetamab, or to BCMA CAR-T (Abecma or Carvykti). For patients with active HBV without adequate antiviral coverage, daratumumab initiation is deferred until HBV control is achieved. For patients with grade 3+ infusion reaction to the first IV dose, the SC formulation may be tolerated; persistent grade 3+ reaction across both formulations requires discontinuation and a non-CD38 regimen.

For AL amyloidosis with advanced cardiac staging (Mayo Stage IIIb), the initiation conversation is more delicate; D-VCd is still the standard first-line but treatment 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

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We are a US-based concierge coordinator. We are not the prescriber and not the dispensing pharmacy. On a UAE 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 Thiqa, Daman, 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.

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### **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.

Reserve Meds is in pre-launch. Published timelines and cost ranges are indicative, not guarantees.

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