

Darzalex Faspro® (daratumumab/hyaluronidase-fihj) – New indication

- On July 30, 2024, the [FDA announced](#) the approval of [Johnson & Johnson's Darzalex Faspro \(daratumumab/hyaluronidase-fihj\)](#), for the treatment of adult patients with multiple myeloma in combination with bortezomib, lenalidomide, and dexamethasone (D-VRd) for induction and consolidation in newly diagnosed patients who are eligible for autologous stem cell transplant (ASCT).
- Darzalex Faspro is also approved for seven other multiple myeloma indications and for light chain amyloidosis.
- The approval of Darzalex Faspro for the new indication was based on an open-label, randomized, active-controlled study in 709 patients. Patients received D-VRd or bortezomib, lenalidomide and dexamethasone (VRd). The major efficacy outcome measure was progression-free survival (PFS).
 - Treatment with D-VRd resulted in a reduction in the risk of disease progression or death by 60% vs. VRd alone (Hazard ratio, 0.40; 95% CI: 0.29, 0.57; $p < 0.0001$).
 - The median PFS was not reached in either arm.
- The most common adverse reactions ($\geq 20\%$) with Darzalex Faspro and VRd use in multiple myeloma were peripheral neuropathy, fatigue, edema, pyrexia, upper respiratory infection, constipation, diarrhea, musculoskeletal pain, insomnia, and rash.
- The recommended dose of Darzalex Faspro for the treatment of the new indication is 1,800 mg/30,000 units (1,800 mg daratumumab and 30,000 units hyaluronidase) administered subcutaneously over approximately 3-5 minutes and in the schedule as follows:

Treatment Phase	Weeks	Schedule
Induction	weeks 1-8	weekly (total of 8 doses)
	weeks 9-16 ^a	every 2 weeks (total of 4 doses)
Stop for high dose chemotherapy and ASCT		
Consolidation	weeks 1-8 ^b	every two weeks (total of 4 doses)

^a First dose of the every-2-week dosing schedule is given at week 9
^b First dose of the every-2-week dosing schedule is given at week 1 upon re-initiation of treatment following ASCT

- Refer to individual drug labels for dosage recommendations for the other drugs.
- Refer to the Darzalex Faspro drug label for dosing for all its other indications.