



Darzalex[®]

(daratumumab) injection

Darzalex, a highly effective new medication to treat myeloma, is a laboratory-made monoclonal antibody that targets a specific single protein on the surface of myeloma cells. Of the four therapies for myeloma approved in 2015 by the US Food and Drug Administration (FDA), only Darzalex has single-agent activity and was approved based on its superiority to existing treatments for myeloma.

Who is a candidate for Darzalex?

In the United States, Darzalex is approved for the following indications:

- As a single agent for myeloma patients who have received at least three prior lines of therapy, including a proteasome inhibitor (PI) and an immunomodulatory drug, or who are double-refractory to a PI and an immunomodulatory drug.
- In combination with Revlimid + dexamethasone (Rd) or Velcade + dexamethasone (Vd) for the treatment of myeloma patients who have received at least one prior therapy.
- In combination with Pomalyst + dexamethasone (Pd) for the treatment of myeloma patients who have received at least two prior therapies, including Revlimid and a PI.
- In combination with Velcade + melphalan + prednisone (VMP) for the treatment of patients with newly diagnosed myeloma who are ineligible for autologous stem cell transplant (ASCT).

In the European Union, Darzalex is approved for the following indications:

- As a single agent for monotherapy of adult patients with relapsed and refractory myeloma, whose prior therapy included a PI and an immunomodulatory drug, and who have demonstrated disease progression on the last therapy.
- In combination with Rd or Vd for the treatment of myeloma patients who have received at least one prior therapy.

How is Darzalex given?

- The dose of Darzalex, whether alone or in combination with Revlimid + dexamethasone, is 16 mg/kg of body weight. It is given weekly for weeks 1–8, every 2 weeks for weeks 9–24, and every 4 weeks for weeks 25 onward until disease progression.
- In combination with Velcade + dexamethasone, Darzalex is given at the standard dose, but is given weekly for weeks 1–9,

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every 3 weeks for weeks 10–24, and every 4 weeks for weeks 25 onward until disease progression.

- The first dose of Darzalex is usually given over a period of up to 8 hours. The slow infusion rate makes it less likely that a severe infusion reaction will occur. If it is well tolerated, subsequent doses can be given more rapidly, at your doctor's discretion. Medications are given before and after each Darzalex infusion to help prevent a reaction.

Possible side effects of Darzalex

- Side effects that occurred in 20% or more of the patients in the Darzalex registration clinical trials were infusion reactions, fatigue, nausea, back pain, fever, cough, and upper respiratory tract infection.
- Darzalex may cause blood cell counts to drop, with significant numbers of patients experiencing low red blood cell counts (anemia), low platelet counts (thrombocytopenia), and low white blood cell counts (neutropenia and lymphopenia).
- Darzalex can cause reactivation of the herpes zoster virus (the virus that causes chicken pox, which, when reactivated, causes shingles), so all patients should receive preventive treatment with an anti-viral medication.

Special cautions with Darzalex

- Darzalex interferes with blood compatibility testing, including antibody screening and cross-matching done prior to blood transfusions. Your doctor should type and screen your blood before you start treatment with Darzalex in case you need a blood transfusion subsequently.
- There are no human data to inform a risk with use of Darzalex during pregnancy but, in general, anti-cancer agents and monoclonal antibodies may cause fetal harm. Women of reproductive potential should use effective contraception during treatment and for 3 months after stopping Darzalex treatment.

Darzalex patient resources

Janssen Pharmaceuticals has a CarePath program to help support patients who are receiving treatment with Darzalex. Visit darzalex.com or call 844.553.2792.

As always, the IMF urges you to discuss all medical issues with your doctor, and to contact the IMF with your myeloma questions and concerns.

International Myeloma Foundation

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