

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 US, Darzalex is indicated:

- in combination with Revlimid + dexamethasone, or Velcade + dexamethasone, for the treatment of patients with myeloma who have received at least one prior therapy, and
- as monotherapy, for the treatment of patients with myeloma who have received at least three prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent, or who are double-refractory to a PI and an immunomodulatory agent.

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, every 3 weeks for weeks 10–24, and every 4 weeks for weeks 25 onward until disease progression.
- Especially with the first dose, the infusion rate for Darzalex is very slow. The slower, the less likely it is that a severe infusion reaction will occur. The first dose is usually given over a period of up to 8 hours. If it is well tolerated, subsequent doses will be given more rapidly, at your doctor's discretion. Medications are given before and after each Darzalex infusion to help prevent a reaction.

The IMF InfoLine is staffed by trained information specialists.

800.452.CURE (2873) *in the US & Canada*



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Myeloma
Foundation[®]

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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).

Because Darzalex can cause reactivation of the herpes zoster virus (the virus that causes chicken pox, which, when reactivated, causes shingles), 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.

Darzalex may interfere with serum protein electrophoresis (SPEP) and immunofixation electrophoresis (IFE) tests. This can lead to false positive test results for patients with IgG kappa myeloma protein, leading to inaccuracies in detecting complete response and disease progression.

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 for information about myeloma.

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