



# Darzalex<sup>®</sup>

## (daratumumab) injection

Darzalex 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.

### Who is a candidate for Darzalex?

**In the US, Darzalex is indicated for the treatment of adult patients with myeloma:**

- in combination with Revlimid<sup>®</sup> (lenalidomide) + dexamethasone (Rd) in newly diagnosed patients who are ineligible for autologous stem cell transplant (ASCT) and in patients with relapsed or refractory myeloma who have received at least one prior therapy,
- in combination with Velcade<sup>®</sup> (bortezomib) + melphalan + prednisone (VMP) in newly diagnosed patients who are ineligible for ASCT,
- in combination with Velcade + dexamethasone (Vd) in patients who have received at least one prior therapy,
- in combination with Pomalyst<sup>®</sup> (pomalidomide) + dexamethasone (Pd) in patients who have received at least two prior therapies including Revlimid + a proteasome inhibitor (Kyprolis<sup>®</sup> [carfilzomib], Ninlaro<sup>®</sup> [ixazomib], or Velcade),
- as monotherapy in patients who have received at least three prior lines of therapy including a proteasome inhibitor + an immunomodulatory drug (Pomalyst, Revlimid, or thalidomide), or who are double-refractory to a proteasome inhibitor and an immunomodulatory agent.

### How is Darzalex given?

**Darzalex is administered intravenously at the dose of 16 mg/kg of body weight in accordance with the following schedules:**

- In combination with Pomalyst or Revlimid (4-week cycle dosing regimens) and low-dose dexamethasone and for monotherapy:
  - Weeks 1–8: weekly (total of 8 doses)
  - Weeks 9–24: every 2 weeks (total of 8 doses)
  - Week 25 onward: every 4 weeks
- In combination with VMP (6-week dosing regimen):
  - Weeks 1–6: weekly (total of 6 doses)
  - Weeks 7–54: every 3 weeks (total of 16 doses)
  - Week 55 onward: every 4 weeks

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- in combination with Vd (3-week cycle dosing regimen):
  - Weeks 1–9: weekly (total of 9 doses)
  - Weeks 10–24: every 3 weeks (total of 5 doses)
  - Week 25 onward: every 4 weeks

***The option to split the first infusion of Darzalex over two consecutive days has been approved in both the US and Europe.***

## **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 can be detected on both the serum protein electrophoresis (SPEP) and immunofixation (IFE) assays used for the clinical monitoring of M-protein. This interference can impact the determination of complete response (CR) and of disease progression in some patients with IgG kappa myeloma protein.

## **Darzalex patient resources**

Visit [darzalex.com](http://darzalex.com) or call 844.553.2792 for information about the Janssen Pharmaceuticals CarePath program.

***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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