



# **DARZALEX<sup>®</sup>** **(daratumumab)** **intravenous infusion**

Darzalex is the first FDA-approved monoclonal antibody that targets the CD38 protein on the surface of myeloma cells.

## **Who is a candidate for Darzalex?**

**In the US, Darzalex is FDA-approved for the treatment of adult patients with myeloma.**

- In newly diagnosed patients who are eligible for autologous stem cell transplant (ASCT), in combination with Velcade<sup>®</sup> (bortezomib) + thalidomide + dexamethasone (VTd).
- In newly diagnosed patients who are ineligible for ASCT, in combination with Revlimid<sup>®</sup> (lenalidomide) + dexamethasone (Rd), or Velcade + melphalan + prednisone (VMP).
- In patients who have received at least 1 prior therapy, in combination with Velcade + dexamethasone (Vd).
- In patients with relapsed or refractory myeloma who have received 1 to 3 previous lines of therapy, in combination with Kyprolis<sup>®</sup> (carfilzomib) + dexamethasone (Kd).
- In patients who have received at least 2 prior therapies including Revlimid + a proteasome inhibitor (Kyprolis, Ninlaro<sup>®</sup> [ixazomib], or Velcade), in combination with Pomalyst<sup>®</sup> (pomalidomide) + dexamethasone (Pd).
- As monotherapy in patients who have received at least 3 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 drug.

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## How is Darzalex given?

- The original formulation of Darzalex is administered intravenously (infused into the vein, IV) at the dose of 16 mg/kg of body weight. The first dose is usually given over a period of up to 8 hours. Especially with the first dose, the slower the rate of infusion, the less likely it is that a severe infusion reaction will occur. If the Darzalex infusion is well tolerated, subsequent doses may be given more rapidly at your doctor's discretion. The FDA has also approved a regimen that allows doctors to split the first IV infusion over two consecutive days. Medications are given before and after each infusion to help prevent a reaction.

## Possible side effects of Darzalex

- Side effects that occurred in  $\geq 20\%$  of the patients in the Darzalex registration clinical trials were infusion reactions, fatigue, nausea, back pain, fever, cough, and upper respiratory tract infection. Be sure to contact your doctor with your concerns.
- Darzalex may cause blood cell counts to drop, with patients experiencing anemia, thrombocytopenia, neutropenia, and lymphopenia. Your doctor will monitor your blood counts, and a reduction in the dose of Darzalex may be required.
- Darzalex can cause reactivation of the herpes zoster virus (shingles). All patients should receive preventive treatment with an antiviral medication.
- If you have ever had a hepatitis B virus (HBV) infection, Darzalex can cause it to become active again at any treatment phase. Your doctor will monitor you before, during, and for some time after treatment with Darzalex.

## Special precautions with Darzalex

- Darzalex interferes with blood compatibility testing. Your doctor will type and screen your blood before you start treatment with Darzalex in case you need a blood transfusion subsequently.
- Women of reproductive potential should use effective contraception during treatment with Darzalex 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 Faspro™** **(daratumumab and hyaluronidase-fihj) subcutaneous injection**

Darzalex Faspro is a combination of daratumumab + hyaluronidase (an endoglycosidase), a new formulation that is given as an abdominal injection under the skin (subcutaneously, SQ). Darzalex Faspro has been determined to be equally effective when compared to the original formulation of Darzalex. Switching from IV to SQ must first be discussed with your doctor.

## **Who is a candidate for Darzalex Faspro?**

**Darzalex Faspro is used in myeloma as part of the following treatments:**

- In newly diagnosed patients who are ineligible for ASCT, in combination with Rd or VMP.
- In patients who have received at least 1 prior therapy, in combination with Vd.
- As monotherapy in patients who have received at least 3 prior lines of therapy, including a proteasome inhibitor + an immunomodulatory drug, or who are double-refractory to a proteasome inhibitor and an immunomodulatory drug.

## **How is Darzalex Faspro given?**

- Darzalex Faspro is given by a healthcare professional as an abdominal SQ injection that takes only a few minutes. The dose is 1,800 mg daratumumab + 30,000 units hyaluronidase per 15 mL (120 mg and 2,000 units/mL) solution in a single-dose vial.

## **Possible adverse reactions to Darzalex Faspro**

- The most common hematological abnormalities in laboratory tests ( $\geq 40\%$ ) with Darzalex Faspro are decreased leukocytes, decreased lymphocytes, decreased neutrophils, decreased platelets, and decreased hemoglobin. Your doctor will monitor your blood counts.

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- Be sure to report your concerns to your doctor. The most common side effects ( $\geq 20\%$ ) with Darzalex Faspro are:
  - **With monotherapy:** Upper respiratory tract infection.
  - **With combination therapy:** Fatigue, nausea, diarrhea, shortness of breath, trouble sleeping, fever, cough, muscle spasms, back pain, vomiting, cold-like symptoms (upper respiratory tract infection), peripheral neuropathy (nerve damage causing tingling, numbness, or pain), constipation, and lung infection (pneumonia).

## Special precautions with Darzalex Faspro

- **Hypersensitivity:** Your doctor will discontinue Darzalex Faspro for life-threatening reactions.
- **Neutropenia:** Your doctor will monitor your complete blood cell counts during treatment, and monitor for signs of infection.
- **Thrombocytopenia:** Your doctor will monitor your complete blood cell counts during treatment.
- **Embryo-fetal toxicity:** Darzalex Faspro can cause fetal harm. Females of reproductive potential should use effective contraception.
- **Interference with cross-matching and red blood cell antibody screening:** Your doctor will screen you prior to starting treatment. Blood banks should be informed that you have received Darzalex Faspro.

## Janssen CarePath Program

Please call 1-844-553-2792 or visit [darzalex.com](http://darzalex.com) for more information.

*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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