# Darzalex

(daratumumab)


New Product Slideshow

MPR

# Introduction

- **Brand name:** Darzalex
- **Generic name:** Daratumumab
- **Pharmacological class:** CD38-directed monoclonal antibody
- **Strength and Formulation:** 100mg/5mL, 400mg/20mL; per vial; solution for IV infusion after dilution; contains mannitol; preservative-free
- **Manufacturer:** Janssen Biotech
- **How supplied:** Single-dose vial—1
- **Legal Classification:** Rx

# DARZALEX


DARZALEX™
(daratumumab)
Injection
400 mg/20 mL
(20 mg/mL)
For Intravenous Infusion Only
NDC 57894-502-20
Rx only
DARZALEX™
(daratumumab)
Injection
400 mg/20 mL
(20 mg/mL)
For Intravenous Infusion Only
Dilute Before Use
Single-Dose Only. Discard Unused Portion
janssen
NDC 57894-502-20 Rx Only
DARZALEX™
(daratumumab)
Injection
400 mg/20 mL
(20 mg/mL)
For Intravenous Infusion Only

# Indications

- Treatment of **multiple myeloma** in patients who have received ≥3 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

# Dosage & Administration

- **Premedicate** with IV corticosteroid, oral antipyretic, oral or IV antihistamine 1 hour prior to every infusion; and give oral corticosteroid on the first and second day after all infusions
- Give only as **IV infusion**
- 16mg/kg weekly on Weeks 1–8, every 2 weeks on Weeks 9–24, then every 4 weeks on Week 25 onwards until disease progression

# Dosage & Administration

- **Infusion rates and modifications for infusion reactions:** see full labeling

- **Prophylaxis for herpes zoster reactivation:** initiate antiviral prophylaxis within 1 week of starting therapy and continue for 3 months after treatment

# Considerations for Special Populations

- **Pregnancy:** May cause fetal myeloid or lymphoid-cell depletion and decreased bone density
- **Nursing mothers:** Consider benefits and potential adverse effects
- **Pediatric:** Not established
- **Geriatric:** No overall differences in safety or efficacy
- **Hepatic impairment:** Moderate to severe impairment: not studied

# Warnings/Precautions

- Should be administered by a healthcare professional with immediate access to emergency equipment and appropriate medical support
- **Monitor** for infusion reactions; interrupt treatment for infusion reactions of any severity
- **Permanently discontinue** if life-threatening (Grade 4) infusion reactions occur; for Grade 1, 2, or 3 reactions, reduce the infusion rate when restarting the infusion

# Warnings/Precautions

- History of **obstructive pulmonary disorders:** may require additional post-infusion drugs; consider prescribing short- or long-acting bronchodilators and inhaled corticosteroids
- Interference with cross-matching and RBC antibody screening; type/screen patients prior to initiating treatment
- Females of reproductive potential should **use effective contraception** during treatment and for 3 months after

# Interactions

- Interferes with Indirect Antiglobulin (Coombs) Test, serum protein electrophoresis and immunofixation assays leading to false (+) results

# Adverse Reactions

- Infusion reactions
- Fatigue
- Nausea
- Back pain
- Pyrexia
- Cough
- Upper respiratory tract infection

# Mechanism of Action

- Daratumumab is an immunoglobulin G1 kappa human monoclonal antibody that binds to CD38 and inhibits the growth of CD38 expressing tumor cells
- It exerts its action by inducing apoptosis directly through Fc mediated cross linking and immune-mediated tumor cell lysis through complement dependent cytotoxicity, antibody dependent cell mediated cytotoxicity, and antibody dependent cellular phagocytosis

# Clinical Trials

- **Study 1** was an open-label trial evaluating Darzalex monotherapy in 106 patients with relapsed or refractory multiple myeloma who had received ≥3 prior lines of therapy including a PI and an immunomodulatory agent or who were double-refractory to a PI and an immunomodulatory agent
- The **primary endpoint** was overall response rate (ORR) as determined by the Independent Review Committee assessment using International Myeloma Working Group criteria

# Clinical Trials

- **Study 2** was an open-label dose escalation trial evaluating Darzalex monotherapy in 42 patients with relapsed or refractory multiple myeloma who had received ≥2 different cytoreductive therapies
- In both studies, Darzalex 16mg/kg was administered with pre- and post-infusion medications
- Treatment was continued until unacceptable toxicity or disease progression

# Clinical Trials

- Efficacy results from **Study 1** showed an ORR of 29.2% for Darzalex (95% CI: 20.8, 38.9), with a median time to response of 1 month (range: 0.9–5.6 months) and a median duration of response of 7.4 months (range: 1.2–13.1+ months)

- In **Study 2**, ORR was 36% (95% CI: 21.6, 52) for Darzalex, with a median time to response of 1 month (range: 0.5–3.2 months)

# Clinical Trials

- The median duration of response was not estimable for **Study 2** (range: 2.2–13.1+ months)

- For more clinical trial data, see full labeling

# New Product Monograph

- For more information view the complete product monograph available at:

  http://www.empr.com/darzalex/drugproduct/401/