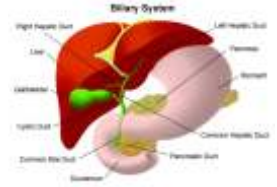


**Rx** **DARBEPOETIN ALFA**  
(It is an erythropoiesis stimulating protein, closely related to erythropoietin)



**Darbeпоetin alfa** is an erythropoiesis stimulating protein, closely related to erythropoietin, that is produced in Chinese hamster ovary (CHO) cells by recombinant DNA technology. Darbeпоetin alfa is a 165-amino acid protein that differs from recombinant human erythropoietin in containing 5 N-linked oligosaccharide chains, whereas recombinant human erythropoietin contains 3 chains.<sup>1</sup> The two additional N-glycosylation sites result from amino acid substitutions in the erythropoietin peptide backbone. The additional carbohydrate chains increase the approximate molecular weight of the glycoprotein from 30,000 to 37,000 daltons. Darbeпоetin alfa is formulated as a sterile, colorless, preservative-free protein solution for intravenous or subcutaneous administration.

**DRUG INTERACTIONS**

Tell your doctor of all prescription and nonprescription medication you may use, especially: other blood-related products (e.g., erythropoietin alfa). Do not start or stop any medicine without doctor or pharmacist approval.

**USES**

Darbeпоetin alfa is used to treat low red blood cell counts (anemia) either in people with long-term kidney failure (chronic renal failure) or in people with certain types of cancer (non-myeloid) who are receiving chemotherapy. It works by stimulating the bone marrow to make more red blood cells.

**HOW TO USE:**

Learn how to prepare and inject the drug and review the darbeпоetin alfa Patient Information Booklet. If any of the information is unclear, consult your doctor or pharmacist. Do not shake the vial or syringe and do not mix this drug with IV solutions or other injectable drugs. Consult your pharmacist. Inject this medication into a vein (IV) or under the skin (SC) usually once weekly; or as directed by your doctor. The dosage is based on your weight, medical condition, and response to therapy. Use this medication exactly as prescribed. Do not increase your dose, use it more frequently, or use it for a longer period of time than prescribed because doing so may increase your chance for serious side effects. It may take up to 4 weeks before the full benefit of this drug takes effect. Before using, check this product visually for particles or discoloration. If either is present, do not use the liquid. Learn how to store and discard needles and medical supplies safely. Consult your pharmacist.

**SIDE EFFECTS**

Headache, diarrhea, nausea, vomiting, cough, or constipation may occur. If any of these effects persist or worsen, notify your doctor. Tell your doctor immediately if any of these serious side effects occur: pain/irritation/redness/bruising at the injection site, other pain (e.g., muscle, joint, back, stomach, or chest pain), unusual tiredness/weakness, swelling of the arms/legs. Tell your doctor immediately if any of these unlikely but serious side effects occur: flu-like symptoms (e.g., fever, chills, sore throat, muscle aches), blurred vision, irregular heartbeat, severe chest pain, shortness of breath, pain in the legs or groin. Tell your doctor immediately if any of these highly unlikely but very serious side effects occur: seizures, one-sided weakness, slurred speech, confusion. An allergic reaction to this drug is unlikely, but seek immediate medical attention if it occurs. Symptoms of an allergic reaction include: rash, itching, swelling, dizziness, trouble breathing. If you notice other effects not listed above, contact your doctor or pharmacist.

**PRECAUTIONS**

This medication is not recommended for use if you have the following medical conditions: uncontrolled high blood pressure. Tell your doctor your medical history, especially of: heart problems, other blood disorders (e.g., sickle cell anemia, porphyria), vitamin deficiencies (e.g., B-12, folate), seizures, high blood pressure (treated or controlled), recent infections or injury, cancer, inflammatory conditions (e.g., bowel disease, rheumatoid arthritis), any allergies. This medication should be used only when clearly needed during pregnancy. Discuss the risks and benefits with your doctor. It is not known if this drug passes into breast milk. Consult your doctor before breast-feeding.

**OVERDOSE**

If overdose is suspected, contact your local poison control center or

emergency room immediately. US residents can call the US national poison hotline at 1-800-222-1222. Canadian residents should call their local poison control center directly.

**MISSED DOSE**

If you miss a dose, use it as soon as you remember. If it is near the time of the next dose, skip the missed dose and resume your usual dosing schedule. Do not double the dose to catch up.

**STORAGE**

Store refrigerated between 36 and 46 degrees F (2 and 8 degrees C) away from light. Do not freeze or shake the vials or syringes. Discard any unused portion of the vial or syringe.

**WARNING**

Darbeпоetin alfa injection increases the risk of blood clots forming in or moving to the legs, lungs, or brain. Call your doctor immediately if you experience any of the following symptoms: pain, tenderness, redness, warmth, and/or swelling in the legs; coolness or paleness in an arm or leg; shortness of breath; cough that won't go away or that brings up blood; chest pain; sudden trouble seeing in one or both eyes; sudden trouble speaking or understanding speech; sudden confusion; sudden weakness or numbness of an arm or leg (especially on one side of the body) or of the face; sudden trouble walking, dizziness, or loss of balance or coordination; sudden severe headache; or seizures.

Using darbeпоetin alfa injection increases the risk that you will develop a blood clot during or after surgery. Before you have surgery, tell your doctor that you are using darbeпоetin alfa injection. Your doctor may prescribe an anticoagulant ('blood thinner') to help prevent blood clots from forming during or after surgery.

Your doctor will adjust your dose of darbeпоetin alfa injection so that your hemoglobin level (amount of a protein found in red blood cells) is between 10-12 g/dL. If your hemoglobin level is higher than this, there is a greater risk that you will develop serious side effects including heart attack, stroke, heart failure, blood clots, and death. Call your doctor immediately if you experience any of the following symptoms: chest pain, squeezing pressure, or tightness; shortness of breath; nausea, lightheadedness, sweating, and other early signs of heart attack; discomfort or pain in the arms, shoulder, neck, jaw, or back; fast or irregular heartbeat; swelling of the hands, feet, or ankles; blue-grey coloring or darkening around mouth or nails; extreme tiredness or weakness; or fainting or loss of consciousness.

**Note :** This product information is intended only for residents of the India. Taj Pharmaceuticals Limited, medicines help to treat and prevent a range of conditions—from the most common to the most challenging—for people around the world.



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