



Darbepoetin Alfa Injection

(dar be poe' e tin)

Contents of this page:

- [Why is this medication prescribed?](#)
- [How should this medicine be used?](#)
- [Other uses for this medicine](#)
- [What special precautions should I follow?](#)
- [What special dietary instructions should I follow?](#)
- [What should I do if I forget a dose?](#)
- [What side effects can this medication cause?](#)
- [What storage conditions are needed for this medicine?](#)
- [In case of emergency/overdose](#)
- [What other information should I know?](#)
- [Brand names](#)

IMPORTANT WARNING:

[UPDATE 12/02/2008] FDA issued Q&As for recently approved Medication Guides. The Medication Guides were developed to provide patients with important information about the risks of using ESAs. The information in the Medication Guides may affect a patient's decision to take the drug and it gives patients a starting point for discussion with their healthcare provider about the medical decision to prescribe an ESA. For more information visit the FDA website at: <http://www.fda.gov/Safety/MedWatch>, <http://www.fda.gov/Drugs>, <http://www.fda.gov/Drugs>, <http://www.fda.gov/Drugs> and <http://www.fda.gov/Safety/MedWatch>.

IMPORTANT WARNING:

All patients:

Darbepoetin alfa 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; 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 or loss of balance or coordination; sudden severe headache; or seizure.

Using darbepoetin alfa 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 darbepoetin alfa. Your doctor may prescribe an anticoagulant ('blood thinner') to help prevent blood clots from forming during or after surgery.

Keep all appointments with your doctor and the laboratory. Your doctor will order certain lab tests to check your body's response to darbepoetin alfa. Your doctor may decrease your dose or tell you to stop using darbepoetin alfa for a period of time if the tests show that you are at high risk of experiencing serious side effects. Follow your doctor's directions carefully.

Talk to your doctor about the risks of using darbepoetin alfa.

Patients with chronic renal failure:

Your doctor will adjust your dose of darbepoetin alfa so that your hemoglobin level (amount of a protein found in red blood cells) is between 10-12g/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.

If you are receiving hemodialysis (treatment in which the blood is passed through a filter to remove wastes that would normally be removed by the kidneys), you may develop a blood clot in your vascular access (place on your body where your blood is removed and returned during dialysis). Call your doctor right away if you think you have a blood clot in your vascular access.

Cancer patients:

In clinical studies, people with certain cancers who received darbepoetin alfa died sooner or experienced tumor growth, a return of their cancer, or cancer that spread sooner than people who did not receive the medication. If you have cancer, there is a risk that your tumor will return, grow faster, or you will die sooner if you receive darbepoetin alfa. To decrease these risks, you should receive the lowest possible dose of darbepoetin alfa and you should only receive darbepoetin alfa when you are receiving chemotherapy to treat your symptoms, rather than to cure your cancer. Treatment with darbepoetin alfa should be stopped when your course of chemotherapy ends.

Why is this medication prescribed?

Darbepoetin alfa is used to treat anemia (a lower than normal number of red blood cells) in people with chronic kidney failure (condition in which the kidneys slowly and permanently stop working over a period of time). Darbepoetin alfa is also used to treat anemia caused by chemotherapy (medications to treat cancer). Darbepoetin alfa is in a class of medications called erythropoiesis-stimulating agents (ESAs). It works by causing the bone marrow (soft tissue inside the bones where blood is made) to make more red blood cells.

How should this medicine be used?

Pending revision, the material in this section should be considered in light of more recently available information in the MedWatch notification at the beginning of this monograph.

Darbepoetin alfa comes as a solution (liquid) to inject subcutaneously (just under the skin) or intravenously (into a vein). It is usually injected once a week every 1 to 3 weeks. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Use darbepoetin alfa exactly as directed. Do not use more or less of it or use it more often than prescribed by your doctor.

Your doctor may start you on the lowest possible dose of darbepoetin alfa and gradually increase or decrease your dose, not more than once every month. Your doctor may also tell you to stop using darbepoetin alfa for a time. Follow these instructions carefully. If your doctor tells you to stop using darbepoetin alfa, do not begin using it again until your doctor tells you that you should. It is likely that your doctor will restart your treatment with a lower dose of darbepoetin alfa than you were using.

Darbepoetin alfa is used to reduce the need for red blood cell transfusions. Darbepoetin alfa controls anemia but does not cure it. It may take 2 to 6 weeks or longer before you feel the full benefit of darbepoetin alfa. Continue to use darbepoetin alfa even if you feel well. Do not stop using darbepoetin alfa without talking to your doctor.

Darbepoetin alfa injections are usually given by a doctor or nurse. Your doctor may decide that you can inject darbepoetin alfa yourself, or that you may have a friend or relative give the injections. Your doctor will train the person who will be injecting the medication and will test him to be sure he can give the injection correctly. Be sure that you and the person who will be giving the injections know the correct dose, how to give the medication, and how often to give the medication. Be sure that you and the person who will be giving the injections read the manufacturer's information for the patient that comes with darbepoetin alfa before you use it for the first time at home.

Darbepoetin alfa comes in prefilled syringes and also in vials to use with disposable syringes. Use vials and prefilled or disposable syringes only once. Do not put a needle through the rubber stopper of a vial more than once. Throw away a vial, syringe, or prefilled syringe after one use, even if it is not empty. Throw away used syringes in a puncture-resistant container, out of the reach of children. Do not throw a filled container into the household trash or recycling. Talk to your doctor or pharmacist about how to throw away the puncture-resistant container. There may be special state and local laws for throwing away used needles and syringes.

If you are using vials of darbepoetin alfa, you will need to use disposable syringes to inject your medication. Your doctor or pharmacist will tell you what type of syringe you should use. Do not use any other type of syringe because you may not get the right amount of medication.

Always inject darbepoetin alfa solution in its own syringe; never mix it with any other medication.

If you are injecting darbepoetin alfa subcutaneously, you can inject it just under the skin anywhere on these parts of your body: the outer area of your upper arms, your stomach except for the 2-inch (5-centimeter) area around your navel (belly button), the front of your middle thighs, and the upper outer areas of your buttocks.

Choose a new spot each time you inject darbepoetin alfa. Do not inject darbepoetin alfa into a spot that is tender, red, bruised, hard, lumpy, or swollen.

Carefully read the manufacturer's instructions that describe how to prepare and inject a dose of darbepoetin alfa. Be sure to ask your pharmacist or doctor if you have any questions about how to prepare or inject this medication.

Ask your pharmacist or doctor for a copy of the manufacturer's information for the patient.

Other uses for this medicine

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

What special precautions should I follow?

Pending revision, the material in this section should be considered in light of more recently available information in the MedWatch notification at the beginning of this monograph.

Before using darbepoetin alfa,

- tell your doctor and pharmacist if you are allergic to darbepoetin alfa, epoetin alfa (Epoen, Procrit), medications made from animal cells, albumin, any other medications, latex, or polysorbate 80. Ask your doctor or pharmacist if you don't know if a medication you are allergic to is made from animal cells.
- tell your doctor if you have or have had high blood pressure. Your doctor may tell you not to use darbepoetin alfa.
- tell your doctor and pharmacist what other prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products you are taking or plan to take.
- tell your doctor if you have or have ever had bleeding or blood clotting problems; diseases that affect your blood such as hemolytic anemia (condition where a low number of red blood cells occurs because the cells are being destroyed in the

body); sickle cell disease (an inherited blood disease that causes pain, anemia, and organ damage); thalassemia (an inherited blood disease that causes abnormal development and other problems); or porphyria (an inherited blood disease that may cause skin or nervous system problems); blood clots in your heart, legs, or lungs; a heart attack; high blood pressure; stroke or ministroke (TIA); tumors; heart disease; or any disease that affects your brain or nervous system.

- tell your doctor if you have used darbepoetin alfa or another erythropoietic protein such as epoetin alfa (Epogen, Procrit) in the past. Be sure to tell your doctor if your anemia worsened during your treatment with one of these medications, or if you were ever told to stop using one of these medications.
- tell your doctor if you are pregnant, plan to become pregnant, or are breast-feeding. If you become pregnant while using darbepoetin alfa, call your doctor.
- you should know that your blood pressure may increase while you are using darbepoetin alfa. Your doctor may ask you to check your blood pressure often. Be sure to check your blood pressure as often as your doctor tells you that you should, to call your doctor if your blood pressure is higher than your doctor says it should be, and to take any medications your doctor prescribes to control your blood pressure exactly as directed.
- you should call your doctor if you are planning to travel or if your activity becomes limited, such as spending more time sitting or in bed.

What special dietary instructions should I follow?

If you are following a prescribed special diet because you have kidney disease or high blood pressure, follow it carefully, even if you feel better while using darbepoetin alfa. Darbepoetin alfa will not work unless your body has enough iron. Your doctor or dietician will probably tell you to eat foods that are rich in iron. If you cannot get enough iron from your diet, your doctor may prescribe an iron supplement. Take this supplement exactly as directed.

What should I do if I forget a dose?

Call your doctor to ask what to do if you miss a dose of darbepoetin alfa. Do not use a double dose to make up for a missed one.

What side effects can this medication cause?

Pending revision, the material in this section should be considered in light of more recently available information in the MedWatch notification at the beginning of this monograph.

Darbepoetin alfa may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:

- headache
- nausea
- vomiting
- stomach pain
- diarrhea
- constipation
- body, joint, or muscle aches
- redness, swelling, bruising, itching, or a lump at the spot where you injected darbepoetin alfa

Some side effects can be serious. If you experience any of the following symptoms, or those listed in the IMPORTANT WARNING section, call your doctor immediately:

- rash over the whole body
- itching
- difficulty breathing or swallowing
- wheezing

- hoarseness
- swelling of the face, throat, tongue, lips, eyes, hands, feet, ankles, or lower legs
- dry mouth
- sunken eyes
- decreased urination
- fever, sore throat, chills, cough, and other signs of infection
- feeling cold most of the time
- pale skin

Darbepoetin alfa may cause other side effects. Call your doctor if you have any unusual problems or you do not feel well while using this medication.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online [at <http://www.fda.gov/Safety/MedWatch>] or by phone [1-800-332-1088].

What storage conditions are needed for this medicine?

Keep this medication in the carton it came in, tightly closed, and out of reach of children. Once a vial or prefilled syringe has been taken out of its carton, keep it covered to protect it from room light until the dose is given. Store darbepoetin alfa in the refrigerator, but do not freeze it. Throw away any medication that has been frozen or is outdated or no longer needed. Talk to your pharmacist about the proper disposal of your medication.

When traveling, pack darbepoetin alfa in its original carton in an insulated container with a coolant such as blue ice. To avoid freezing, make sure the darbepoetin alfa vial or prefilled syringe does not touch the coolant. Once you arrive, place darbepoetin alfa in a refrigerator as soon as possible.

In case of emergency/overdose

In case of overdose, call your local poison control center at 1-800-222-1222. If the victim has collapsed or is not breathing, call local emergency services at 911.

Symptoms of overdose may include:

- unusual tiredness, weakness, or lack of energy
- shortness of breath
- cough that won't go away, or coughing up blood
- wheezing
- dizziness or lightheadedness
- swelling around the mouth or eyes
- blue-grey coloring or darkening around mouth or nails
- fast or irregular heartbeat
- sweating
- seizure
- fainting or loss of consciousness
- chest pain, squeezing pressure, or tightness
- discomfort or pain in the arms, shoulder, neck, jaw, or back
- nausea
- vomiting
- sudden weakness or numbness of an arm or leg (especially on one side of the body) or face
- sudden confusion

- sudden trouble speaking or understanding speech
- sudden trouble seeing in one or both eyes
- sudden trouble walking, or loss of balance or coordination
- sudden severe headache
- pain, tenderness, redness, warmth, and/or swelling in the legs
- swelling of the hands, feet, or ankles
- increased blood pressure
- blood clot in hemodialysis access port

What other information should I know?

Pending revision, the material in this section should be considered in light of more recently available information in the MedWatch notification at the beginning of this monograph.

Before having any laboratory test, tell your doctor and the laboratory personnel that you are using darbepoetin alfa.

Do not let anyone else use your medication. Ask your pharmacist any questions you have about refilling your prescription.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

Brand names

- Aranesp®

Last Reviewed - 02/01/2009