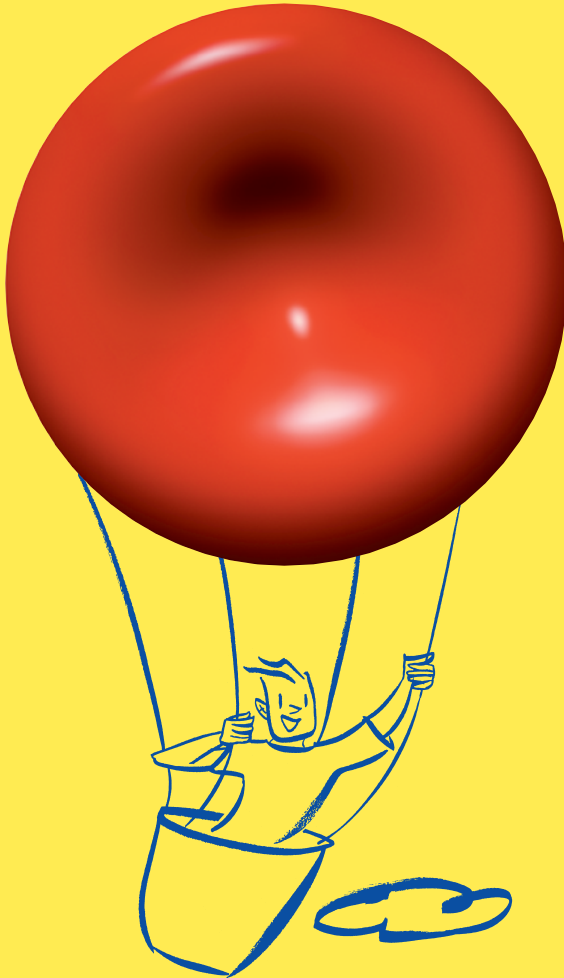


Aranesp[®]
darbepoetin alfa injection

Your Guide to Anemia Management
Patient Information Handbook



AMGEN

● Information for the patient

The following information is intended for patients who will be receiving injections of Aranesp® and for their caregivers. Please read it carefully before taking your dose of Aranesp®. It represents a summary only and therefore does not include all information about Aranesp®. You should discuss any questions about treatment with Aranesp® with your doctor.

● Anemia and chronic kidney disease

Anemia is a condition where your blood does not contain enough red blood cells. Red blood cells are responsible for carrying oxygen to your organs and body tissues. If the number of red blood cells in your blood is decreased, the amount of oxygen delivered throughout your body is also decreased. This may cause several symptoms that are typical of anemia including fatigue, weakness and shortness of breath.

In patients with kidney failure, the kidneys do not produce enough of the natural hormone erythropoietin, which encourages your bone marrow to produce more red blood cells.

● What is Aranesp® used for?

Aranesp® is used to treat anemia associated with chronic kidney disease (kidney failure), including patients on dialysis and patients not on dialysis.

● How does Aranesp® work?

If your kidneys are no longer able to produce enough erythropoietin, you may benefit by receiving Aranesp®. Aranesp® will stimulate your bone marrow to produce more red blood cells. Like the natural hormone erythropoietin, the active ingredient of Aranesp®, “darbepoetin alfa”, travels through the blood and binds to specific cells in the bone marrow. This signals the bone marrow to produce more red blood cells and release them into the blood. As a result, the number of red blood cells circulating in the blood increases and they can deliver more oxygen to your organs and tissues. This helps in managing the symptoms that are associated with anemia. It takes a few weeks for this process to occur.

Your doctor will know when Aranesp® is working because your blood tests will show an increase in the number of red blood cells. He/she may refer to the results of your blood tests as hemoglobin and/or hematocrit, and will check these tests while you are being treated with Aranesp®. These blood tests may be done more often at the

beginning of your treatment or if your dose of Aranesp® changes. The increase in the number of red blood cells is not immediate; it may take several weeks. The amount of time it takes to reach the red blood cell level that is right for you, and the dose of Aranesp® needed to make the red blood cell level rise, is different for each person. You may need several Aranesp® dose adjustments before you reach your correct dose of Aranesp® and the correct dose may change over time. Your doctor will also check your blood pressure regularly. In some cases, your doctor may recommend that you take iron supplements.

You should not take Aranesp® if:

- You have uncontrolled high blood pressure.
- Your body makes antibodies (develop Pure Red Cell Aplasia) following treatment with any erythropoiesis-stimulating agent (ESA).
- You are allergic to Aranesp® or any of the ingredients (for example, polysorbate 80) in Aranesp®.
- You are allergic to other erythropoietins, or medicines made using mammalian cells.

Talk to your doctor if you have any questions about this information.

How is Aranesp® administered?

Aranesp® is given to patients as an injection. The method of injection depends on your clinical condition as indicated below:

- under your skin (subcutaneous); or
- into the venous line connecting the hemodialysis machine to your vein (intravenous), if you are on hemodialysis.

You and your doctor will determine which is best for you. Your doctor will determine how much you must take, and how often you need to take it. Aranesp® is given once a week or in some cases, once every two weeks. Your doctor will try to keep your hemoglobin between 100 and 115 g/L, not to exceed 120 g/L.

You should ask your doctor what to do if you miss a dose of Aranesp®.

● How long will it take to feel better?

Because it will take your bone marrow some time to make more red blood cells, it may take a few weeks before you notice any effects.

● What do I need to know before I begin Aranesp® treatment?

All patients:

- To minimize the risks for death and serious cardiovascular (heart and blood vessel-related) side effects and stroke, your doctor will prescribe the recommended dosage for each indication.
- Patients with uncontrolled high blood pressure should not be treated with Aranesp®; blood pressure should be adequately controlled before receiving Aranesp®.
- Aranesp® should be used with caution in patients with a history of seizures.
- Antibody-mediated Pure Red Cell Aplasia (PRCA) has been reported after months to years of treatment with erythropoiesis-stimulating agents (ESAs). If you develop PRCA, you may suddenly become severely anemic and this could result in a dependency on blood transfusions.

Chronic kidney disease patients:

- If your hemoglobin is kept too high, you have an increased chance of heart attack, stroke, heart failure, blood clots and death. Your doctor will try to keep your hemoglobin between 100 and 115 g/L, not to exceed 120 g/L.

Too much Aranesp® may cause your body to produce too many red blood cells too fast (leading to a hemoglobin that is too high). Producing too many red blood cells, or producing them too fast, may cause serious problems. It is important that your blood pressure be monitored often and to report any changes outside of the guidelines that your doctor has given you, especially if you have heart disease. Certain laboratory tests, such as hemoglobin, hematocrit, or iron level measurements, may also need to be done more often and be reported to your doctor or dialysis centre.

It is important to keep all appointments for blood tests to allow your doctor to adjust the dosage of Aranesp® as needed.

Over time, many patients also need to take iron. Your doctor will know when or if you need an iron supplement from your laboratory test results. Do not change the dose of Aranesp®.

Be sure to change the site for each injection to avoid soreness at any one site. Occasionally, a problem may develop at the injection site. If there is a lump, swelling, or bruising at the injection site that does not go away, talk to your doctor.

Special Warnings

Please tell your doctor if you are suffering or have suffered from:

- high blood pressure;
- heart disease (e.g. angina);
- epileptic fits (seizures).

It is important to tell your doctor if you:

- are pregnant;
- think you may be pregnant;
- plan to get pregnant;
- are breast-feeding.

The following may interact with Aranesp®

No drug-drug interaction studies for Aranesp® have been carried out with other medications commonly used to treat chronic kidney disease.

What are the possible side effects from using Aranesp®?

These are not all the possible side effects you may have when taking Aranesp®. If you experience any side effects not listed here, tell your healthcare professional.

If you get headaches, particularly sudden stabbing migraine-like headaches, or you start to feel confused or have seizures, you should tell your doctor immediately. These may be the warning signs of a sudden rise in blood pressure and may need urgent treatment.

For hemodialysis patients there may be a chance of blood clots (thrombosis) forming in your vascular access (a channel that bypasses normal blood circulation).

You may notice stinging around the area that you were injected. This stinging will only last for a short period of time and may be more common at the start of your treatment. Some people have also had infections, fevers, headaches, muscle aches or soreness, nausea, and chest pain. If you experience any of these symptoms, you should call your doctor. If any of these symptoms persist or you notice any side effects that are not mentioned in this leaflet, please tell your healthcare professional.

Other signs that may appear at the site of injection are redness, swelling, or itching. This may indicate an allergy to the components of Aranesp®, or it may indicate a local reaction. If you have a local reaction consult your doctor.

Serious allergic reactions have been observed, including: sudden life-threatening allergic reactions with drop in blood pressure, fast pulse, difficulty breathing and sweating (anaphylaxis), swelling of the face, lips, mouth, tongue or throat (angioedema), shortness of breath (allergic bronchospasm), skin rash/rash over the whole body, or hives. If you think you are having a serious allergic reaction, stop taking Aranesp® and notify your doctor or emergency medical personnel immediately.

How should I store Aranesp®?

You should store Aranesp® in the refrigerator (between 2° and 8°C), but not in the freezer. Do not let Aranesp® freeze and do not use Aranesp® if you think that it has been frozen. You can take Aranesp® out of the refrigerator and let it warm to room temperature (approximately 30 minutes) before injecting it. Aranesp® does not contain any preservative so you should not use it if you have it at room temperature (up to 25°C) for longer than 24 hours.

Always keep the Aranesp® syringes in the original pack and do not leave them in direct sunlight.

The expiry date for Aranesp® is stamped on the pack and on the syringe label. Do not use Aranesp® after the last day of the month and year shown.

As with all medicines, you should keep Aranesp® out of the reach and sight of children.

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