



**National Kidney
Foundation™**

THE NATIONAL KIDNEY FOUNDATION ANSWERS PATIENTS' CONCERNS ABOUT THE FDA "BLACK BOX" WARNING ON ANEMIA TREATMENT

The Food and Drug Administration (FDA) recently issued a Black Box Warning about the safety of drugs called Erythropoiesis-Stimulating Agents (ESAs) for the treatment of anemia. You may know these drugs as EPO. The National Kidney Foundation (NKF) understands that patients may have concerns about starting or continuing to use ESAs after hearing about the FDA's safety warning. The purpose of these "Frequently Asked Questions" is to help chronic kidney disease (CKD) patients understand the risks and benefits of ESAs for treating anemia and to address concerns you may have about these drugs.

1. WHAT IS ANEMIA?

Anemia means there is a low supply of red blood cells in the body. Red blood cells carry oxygen from your lungs to all your organs and tissues. They provide energy for your daily activities. Having anemia may make you feel tired, look pale, and feel short of breath. Many patients with chronic kidney disease have anemia because their kidneys fail to make enough of a certain hormone. This hormone is called erythropoietin. Erythropoietin helps bone marrow make red blood cells.

2. WHAT IS HEMOGLOBIN?

Hemoglobin is the part of the red blood cell that carries oxygen. Iron is important for making hemoglobin. Doctors measure your hemoglobin level to check if you have anemia. Doctors also use this test when treating anemia to make sure that the hemoglobin level does not become too low or too high.

3. WHAT IS AN FDA "BLACK BOX" WARNING AND WHY WAS ONE ISSUED FOR ESAS?

Black Box Warnings are used by the FDA on drug labels to warn users of serious risks. The drug package insert and ads for drug products with Black Box Warnings must present these serious risks in a way that stands out and is easy to notice.

A Black Box Warning was issued for ESAs because of recent studies that showed an increased risk of death, blood clots, strokes, and heart attacks in patients with CKD (not on dialysis) who used ESAs to treat anemia. The higher risks were seen in patients receiving ESAs at doses designed to raise the hemoglobin higher than the FDA-recommended limit of 12. The Black Box Warning also applies to the use of the ESA to treat anemia in patients who are on dialysis.

In other studies, patients with anemia caused by treatment for head and neck cancers, those with cancer who were not receiving chemotherapy, and patients who had orthopedic surgery all had poor results after ESA treatment for anemia. These results do not apply to most patients with chronic kidney disease.

4. WHAT DRUGS ARE AFFECTED BY THE FDA "BLACK BOX" WARNING ON ANEMIA TREATMENT?

Drugs affected are ESAs called Aranesp, Epogen and Procrit. These drugs are used to treat anemia in chronic kidney disease and other diseases.

5. WHY SHOULD ANEMIA BE TREATED WITH ESA IN CHRONIC KIDNEY DISEASE?

The main reason to treat anemia in chronic kidney disease is to avoid low hemoglobin levels. This will help you have the energy you need to perform your daily activities without feeling tired or short of breath. Treating anemia can improve quality of life by helping you feel better in general and enjoy increased activity.

Before ESAs were developed, patients with anemia had to have red blood cell transfusions to increase their hemoglobin. Today, blood transfusions and their complications can usually be avoided by taking ESAs. Doctors believe that ESAs have fewer risks and are better than blood transfusions for treating anemia.

6. WHAT SHOULD MY HEMOGLOBIN BE IF I HAVE CHRONIC KIDNEY DISEASE?

The FDA does not specify an ideal hemoglobin number. However, the agency states that ESAs should be used at the lowest dose necessary to avoid the need for blood transfusion. The National Kidney Foundation's 2007 *Update of the KDOQI Clinical Practice Guidelines and Recommendations for Hemoglobin Target* advise that the hemoglobin target should generally be in the range of 11 -12 g/dl. The actual level of hemoglobin in an individual patient can fluctuate around that target. The studies the FDA described in the Black Box Warning had a hemoglobin target above the FDA recommended limit of 12.

7. IF I HAVE CHRONIC KIDNEY DISEASE, WHAT SHOULD I DO ABOUT THESE WARNINGS?

If you are being treated with Aranesp, Epogen or Procrit, you should not stop or change the dose of any of these or other drugs without checking with your doctor or other health care provider. You should

also discuss what this FDA Warning means for you and your treatment. While you are treated with ESA for anemia, your hemoglobin level should be checked by your doctor at least once a month. Other blood tests for iron levels should also be checked at least every three months.

If you are not being treated with the ESAs, Aranesp, Epogen or Procrit, you should work with your doctor to see if you have anemia (a low hemoglobin level) that may require treatment. If your doctor finds anemia, other causes such as low levels of iron and other vitamins should be considered before ESA drugs are used. If your health care provider is thinking about treating your anemia with ESAs, you should ask what these recent studies mean for you and your treatment. Ask how you will be monitored to minimize the risk while balancing the benefits to you.

9. WHERE CAN I FIND ADDITIONAL INFORMATION ABOUT ESAS AND ANEMIA?

Visit the National Kidney Foundation's Web site at www.kidney.org. Here you will find more information about the use of ESAs and anemia. You may use the search box to look for definitions of specific terms.

THE NKF ALSO OFFERS THE FOLLOWING BROCHURES:

"Anemia and Chronic Kidney Disease"
11-10-0283 (English); 11-10-0287 (Spanish)

"Managing Anemia When You Are on Dialysis"
11-50-0217 (English); 11-50-0223 (Spanish)

Also, be sure to have a conversation with your doctor or other health care provider. He or she can answer your questions and listen to your concerns about treating anemia in CKD.