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Patient Update: Answers to Your Questions about Health Canada's Safety Bulletin on Anemia Management Drugs

Health Canada recently published new safety and prescribing information about the use of Erythropoiesis-Stimulating Agents (ESAs) to treat anemia. The US Food and Drug Administration also issued a warning about the safety of ESAs. **You may know these drugs as EPO or by the names Aranesp and EPREX.**

These safety warnings may have raised some questions in your mind as to whether you should start or continue to use ESAs. The purpose of this update is to help you understand the benefits and risks of ESAs for treating anemia, and to address concerns you may have about these drugs.

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.

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.

Why has Health Canada issued new safety and prescribing information about ESAs?

Recent studies have shown that CKD patients (not on dialysis) who received ESAs at doses that would raise their hemoglobin higher than the recommended 120 g/L showed an increased risk of death, blood clots, strokes and heart attacks. The Health Canada safety information also applies to the use of the ESA to treat anemia in patients who are on dialysis.

What drugs are affected by this new safety information?

The drugs affected are called Aranesp and EPREX. Working with Health Canada, the drug manufacturers will change the prescribing information for these medicines to reflect the new safety information.



Why should anemia in patients with chronic kidney disease be treated with ESAs?

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.

What should my hemoglobin be if I have chronic kidney disease?

Renal care teams in BC follow the anemia clinical practice guidelines set out by the US National Kidney Foundation (*KDOQI Clinical Practice Guidelines and Clinical Practice Recommendations for Anemia in CKD*). The guidelines advise that the lowest level of hemoglobin should be equal to 110 g/L.

It's important to note the studies that led to the recent safety warnings targeted hemoglobin higher than the recommended limit of 120 g/L.

I have chronic kidney disease. What should I do about these warnings?

If you currently take Aranesp or EPREX for anemia you **should not** stop or change the dose without checking with your doctor. You may want to discuss what this new health safety information means for your treatment program. 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 ESAs right now, you should still have regular blood work to monitor your hemoglobin and iron levels. If you do develop anemia in the future, other causes such as low levels of iron and other vitamins should be considered before ESA drugs are used.

Where can I find additional information about ESAs and anemia?

Two good sources of information are the Kidney Foundation of Canada (www.kidney.ca) and the US National Kidney Foundation (www.kidney.org).