

June 28, 2011

FDA Safety Announcement: Erythropoiesis-Stimulating Agents (ESAs) In Chronic Kidney Disease: Drug Safety Communication - Modified Dosing Recommendations



AUDIENCE: Nephrology, Oncology

ISSUE: The FDA is working to inform healthcare professionals that new modified recommendations for more conservative dosing of Erythropoiesis-Stimulating Agents (ESAs) in patients with chronic kidney disease (CKD) have been approved in order to improve the safe use of these drugs. The FDA made these new recommendations because of data showing increased risks of cardiovascular events with ESAs in this patient population. The new dosing recommendations are based on clinical trials showing that using ESAs to target a hemoglobin level of greater than 11 g/dL in patients with CKD provides no additional benefit than lower target levels, and increases the risk of experiencing serious adverse cardiovascular events, such as heart attack or stroke.

BACKGROUND: ESAs treat certain types of anemia by stimulating the bone marrow to produce red blood cells and by decreasing the need for blood transfusions. The manufacturer has revised the Boxed Warning, Warnings and Precautions, and Dosage and Administration sections of the labels for the ESAs to include this new information.

RECOMMENDATION: Healthcare professionals should weigh the possible benefits of using ESAs to decrease the need for red blood cell transfusions in CKD patients against the increased risks for serious cardiovascular events, and should inform their patients of the current understanding of potential risks and benefits. Therapy should be individualized to the patient and the lowest possible ESA dose given to reduce the need for transfusions. See the [Drug Safety Communication](#) for additional information including a table of key trials and other supporting references. Treatment with ESAs in CKD was discussed at the Cardiovascular and Renal Drugs Advisory Committee, held October 18, 2010. For summary minutes of that Advisory Committee, see link below.

[Summary Minutes of the Cardiovascular and Renal Drugs Advisory Committee](#)

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of this product to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report.htm
- [Download form](#) or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

[Read the MedWatch safety alert, including a link to the FDA recall notice](#)

www.kcercoalition.com/alerts.htm