

SPINE SAFETY WARNING:

**Information for Healthcare Professionals:
Erythropoiesis-Stimulating Agents (ESAs) In Chronic Kidney Disease:
Drug Safety Communication - Modified Dosing Recommendations**

SOURCE: FDA MedWatch

ISSUE: FDA notified 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 to improve the safe use of these drugs. FDA has made these 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 Drug Safety and Risk Management Advisory Committee, held October 18, 2010. For summary minutes of that Advisory Committee, see link below.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products 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 links to the Drug Safety Communication, Press Release, and other information, at:

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm260641.htm>

The North American Spine Society is committed to quality patient care through promotion of patient safety and prevention of medical errors. NASS monitors a variety of government and other resources for patient safety related notices that may be useful to our members. Information from these notices is also archived on the NASS website at <http://www.spine.org/Pages/PracticePolicy/ClinicalCare/SpineSafetyAlerts/Default.aspx>. This information is provided as a service for information and education only.