

Information on Erythropoiesis Stimulating Agents (ESA) (marketed as Procrit, Epogen, and Aranesp)

FDA ALERT [11/16/2006, Updated 2/16/2007 and 3/9/2007]: FDA is issuing this alert to provide new safety information for erythropoiesis-stimulating agents (ESAs) [Aranesp (darbepoetin alfa), Epogen (epoetin alfa), and Procrit (epoetin alfa)]. Analyses of four new studies in patients with cancer found a higher chance of serious and life-threatening side effects and/or death with the use of ESAs. These research studies were evaluating an unapproved dosing regimen, a patient population for which ESAs are not approved, or a new unapproved ESA. In another study, patients scheduled for orthopedic surgery had a higher rate of deep venous thrombosis when treated with Procrit at the approved dose. This new information is consistent with risks found in two clinical studies in patients with chronic renal failure treated with an unapproved regimen of an ESA that were reported in November 2006 and are summarized in the data section below.

All ESAs have the same mechanism of action. As a result, FDA believes these new concerns apply to all ESAs and is re-evaluating how to safely use this product class. FDA and Amgen, the manufacturer of Aranesp, Epogen and Procrit, have changed the full prescribing information for these drugs. The new product labeling includes a new boxed warning, updated warnings, and a change to the dosage and administration sections for all ESAs.

This information reflects FDA's preliminary analysis of data concerning this drug. FDA is considering, but has not reached a final conclusion about, this information. FDA intends to update this sheet when additional information or analyses become available.

- **Healthcare Professional Information**

- Healthcare Professional Sheet [[PDF](#)] or [[HTML](#)] (Updated 3/9/2007)
- Prescribing Information
 - [Epogen and Procrit label and approval history for Drugs@FDA](#)
 - [Aranesp label and approval history for Drugs@FDA](#)

Other Information

- [Public Health Advisory](#) (Issued 3/9/2007)
- [FDA News](#) (Issued 3/9/2007)
- [Questions and Answers](#) (Issued 3/9/2007)

Historical Information

- Healthcare Professional Sheet [[PDF](#)] or [[HTML](#)] (Issued 11/16/2006)
- [Public Health Advisory](#) (Issued 11/16/2006)

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