

February 17, 2010

Erythropoiesis-Stimulating Agents (ESAs): Procrit, Epogen and Aranesp: Drug Safety Communication



FDA and Amgen notified healthcare professionals and patients that all ESAs must be used under a REMS risk management program. As part of the risk management program, a Medication Guide explaining the risks and benefits of ESAs must be provided to all patients receiving an ESA. Under the ESA APPRISE Oncology program, Amgen will ensure that only those hospitals and healthcare professionals who have enrolled and completed training in the program will prescribe and dispense ESAs to patients with cancer.

Amgen is also required to oversee and monitor the program to ensure that hospitals and healthcare professionals are fully compliant with all aspects of the program. FDA is requiring a REMS because studies show that ESAs can increase the risk of tumor growth and shorten survival in patients with cancer who use these products. Studies also show that ESAs can increase the risk of heart attack, heart failure, stroke or blood clots in patients who use these drugs for other conditions.

Patients with chronic kidney failure (includes patients on dialysis and those not on dialysis) using ESAs should:

- Know that the use of ESAs can increase the risk for stroke, heart attack, heart failure, blood clots, and death.
- Read the **Medication Guide** to understand the benefits and risks of using an ESA.
- Get blood tests while using ESAs. The test results may help guide the course of therapy and lower the risks of using these drugs. Patients' healthcare professionals should make them aware of how often to have blood tests.
- Talk with their healthcare professional about any questions they have about the risks and benefits of using ESAs.

Read the complete MedWatch 2010 Safety summary including links to the Drug Safety Communication and current Prescribing Information for these products, at:

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm200391.htm>

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www.kcercoalition.com/alerts.htm