

IMPORTANT DRUG INFORMATION

Dear Dialysis Clinician/Health Care Provider/Pharmacist:

We have been made aware of an outbreak of 21 episodes of bacteremia or pyrogenic reactions in patients receiving EPOGEN® (Epoetin alfa) at a U.S. dialysis unit. A Centers for Disease Control and Prevention investigation revealed that unused portions of EPOGEN® remaining in single dose preservative-free vials were collected and pooled into common vials for use in other patients. These practices were linked to extrinsic bacterial contamination of EPOGEN®. Therefore, multiple entries should not be made into single dose vials, and residual medication from two or more vials should not be pooled into a single vial.

As supplied, EPOGEN® in single dose vials is a sterile solution. Although multidose vials with preservative are available, single dose vials **DO NOT** contain a preservative. Once a syringe has entered a single dose vial, the sterility of the product can no longer be guaranteed. The instructions provided in the labeling for the product under the section “**Preparation and Administration of EPOGEN®**” state:

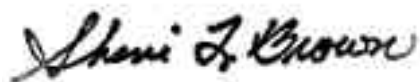
“Single-dose 1 mL vial contains no preservative. Use one dose per vial; do not re-enter vial. Discard unused portions.”

Health care professionals should report any serious adverse events possibly associated with the use of EPOGEN® (Epoetin alfa) to Amgen’s Safety Department (1-800-835-2879 extension 83488). Alternatively, this information may be reported to FDA’s MedWatch reporting system by phone (1-800-FDA-1088), facsimile (1-800-FDA-0178), the MedWatch website at www.fda.gov/medwatch, or mailed to MedWatch, HF-2, 5600 Fishers Lane, Rockville, MD 20852-9787. Both health care professionals and consumers should use the Form 3500 for reporting adverse events.

Should you have any questions or require further information regarding the use of EPOGEN®, please contact Amgen Professional Services at (800) 772-6436.

Please see enclosed full prescribing information.

Sincerely,



Sherri L. Brown, MD
Director, Senior Safety Officer
International Clinical Safety