

Recall - Epogen and Procrit (epoetin alfa)

Certain lots of EPOGEN® and PROCIT® (Epoetin alfa) vials are being voluntarily recalled as a precaution. The product that is being recalled may contain extremely thin glass flakes (lamellae) that are barely visible in most cases. The lamellae result from the interaction of the formulation with glass vials over the shelf life of the product. The potential serious adverse events resulting from the use of a sterile injectable product with particulates by the intravenous route include embolic, thrombotic and other vascular events (e.g., phlebitis), and by the subcutaneous route include foreign body granuloma, local injection site reactions, and increased immunogenicity.

To view the affected product lot numbers and expiration dates please visit <http://www.fda.gov/Safety/Recalls/ucm227202.htm>.

Adverse events related to EPOGEN should be reported to 1-800-77-AMGEN. Adverse events related to PROCIT should be reported to 1-800-547-6446. Consumers with questions regarding this recall can contact Amgen at 1-800-77-AMGEN (open 24 hours per day, 7 days per week) or Centocor Ortho Biotech Products at 1-800-547-6446 (open 24 hours per day, 7 days per week).