



## Important Drug Warning Counterfeiting of EPOGEN(R)

May 8, 2002

### UPDATED INFORMATION

#### IMPORTANT DRUG WARNING COUNTERFEITING OF EPOGEN(R)

May 24, 2002      ADDITIONAL COUNTERFEIT LOTS

Amgen Inc. is updating its information to patients, physicians, pharmacies, and wholesalers to report additional counterfeit EPOGEN(R) (Epoetin alfa). In addition to lot number P002970, discussed in the notice below dated May 8, 2002, the following lot numbers contain counterfeit drug product.

EPOGEN(R) 40,000 U/ml
Lot Number: P001091 Expiration: 09/02
Lot Number: P001486 Expiration: 12/02

Please carefully review the information below in examining EPOGEN(R) before use.

May 8, 2002

Dear Health Care Professional:

Amgen Inc. recently became aware of the existence in the U.S. of a counterfeit drug product labeled as EPOGEN(R) (Epoetin alfa) 40,000 U/ml vials in ten-pack boxes, lot number P002970 and expiration 7/03. In cooperation with the U.S. Food and Drug Administration (FDA), Amgen is informing patients, physicians, pharmacies, and wholesalers about this potentially serious health risk. EPOGEN(R) is primarily used for the treatment of anemia associated with chronic renal failure for patients on dialysis.

**The counterfeit vials examined by Amgen to date contain a clear liquid that contains active ingredient. However, the concentration of active ingredient is approximately 20 times lower than expected for EPOGEN(R) 40,000 U/ml vials.**

Pharmacists and all other health care professionals should carefully examine EPOGEN(R) before use. The following information may help in determining if the product you have is counterfeit.

In order to view pictures illustrating these differences, please log onto Amgen's web site at [www.amgen.com/corporate/AmgenNews.html](http://www.amgen.com/corporate/AmgenNews.html).

Features of authentic EPOGEN(R)	Features of counterfeit product
Amgen logo on carton closure label on exterior of box will shift colors from blue to purple when viewed at different heights. <a href="#">Photo</a>	Amgen logo on carton closure label on exterior of the box lacks color shifting properties (remains blue when viewed at different heights).
Degree sign present for storage temperature on vial label. <a href="#">Photo</a>  "Store at 2 to 8 C"	Degree sign missing from storage temperature on vial label.  "Store at 2 to 8 C"

If you receive any product that you suspect is counterfeit, quarantine it and store it under labeled conditions. Please promptly contact FDA for further instructions at 1 800 835 4709.

If you have questions about EPOGEN(R), please contact Amgen Medical Information at **1 800 772 6436**. Please convey this information to your staff and any others who administer EPOGEN(R). You should instruct them on what to look for and what to do in the event they find a suspect counterfeit vial.

Amgen does not recommend the purchase of Amgen products from wholesalers that do not currently purchase EPOGEN(R) directly from Amgen. A list of wholesalers that currently purchase EPOGEN(R) directly from Amgen can be found on its website at [www.amgen.com/product](http://www.amgen.com/product)

[/productCenter.html](#). The parties on this list are the only wholesalers whom Amgen currently sells to for distribution of its products. If you have purchased Amgen product from another source, you should verify the origin of that product by contacting the distributor.

Amgen is cooperating fully with the FDA to investigate this matter and prevent the further distribution of counterfeit product. To Amgen's knowledge, the counterfeit product has only been found in distribution in the U.S.

Full product information and any updates on this situation are available on the web at [www.amgen.com](http://www.amgen.com).

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Other Contact Information:

U.S. Food and Drug Administration (for press inquiries): (301) 827-6242