

## **Epogen - Important Prescribing Information**

January 2, 2003 SITE DEVELOPMENT COULD CREATE 600 NEW JOBS OVER THE NEXT FOUR YEARS

January 2, 2003

Dear Health Care Professional:

Amgen Inc. has received a single report indicating the product concentration appears to be unclear on the dispensing carton for EPOGEN® 10,000 U/mL Multidose, 2 mL vials. In response to the report, Amgen Inc. is providing this clarifying information to highlight this matter for healthcare providers and patients.

Product concentration is clearly and explicitly stated on every panel of the dispensing carton, on the vial label and package insert as follows:

10,000 Units/1 mL, (20,000 Units/2 mL), 2 mL Multidose Vials 2 mL (20,000 Units, 10,000 Units/mL)

In 2 areas on the dispensing carton, the text considered unclear states:

10 x 10,000 Units/2 mL Multidose Vials

If you have questions regarding EPOGEN 10,000 U/mL Multidose, 2 mL vials, please contact Amgen Medical Information at **1-800-772-6436**. Please convey this information to your staff and any others who administer EPOGEN 10,000 U/mL Multidose, 2 mL vials.

For future packaging, Amgen Inc. is revising the text on the dispensing carton to be consistent with the other, more clearly stated, product concentration statements.

This matter is being conducted with the full knowledge of the Food and Drug Administration.

Full product information, including pictures of the dispensing carton, and any updates on this situation are available on the web at www.amgen.com.

William Sheridan, MB, BS, FRACP Vice President, Medical Affairs Amgen Inc.