AMGEN®
Oncology

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Dear Health Care Professional:

Amgen Inc. wishes to advise you of important changes to the safety information of the product labeling for Aranesp® (darbepoetin alfa) for the treatment of chemotherapy-induced anemia in patients with nonmyeloid malignancies. This safety information has been added to the Aranesp® prescribing information to alert physicians to the adverse effects observed with other products in this class in association with off-label dosing strategies.

Amgen has updated the safety information in the Aranesp® prescribing information to reflect results from two recent investigational studies with other erythropoietic products (ie, epoetin alfa [Eprex®][1] and epoetin beta [NeoRecormon®],[2] conducted outside the US, where patients with cancer were treated to higher hemoglobin target levels beyond the correction of anemia in those patients. These studies permitted or required dosing to achieve hemoglobin levels of greater than 12 grams per deciliter. An increased frequency of adverse patient outcomes, including increased mortality and thrombotic vascular events were reported in these studies. Additional details of these studies are included in the following sections of the revised Aranesp® prescribing information: See WARNINGS – Thrombotic Events and Increased Mortality and PRECAUTIONS – Tumor Growth Factor Potential.

Although these studies were conducted with other erythropoietic products, Amgen has incorporated this information into the aforementioned sections of the Aranesp® prescribing information. This new information does not change the Dosage and Administration section of the Aranesp® prescribing information; Amgen continues to recommend that the target hemoglobin should not exceed 12 grams per deciliter in men or women as indicated in the Aranesp® prescribing information.

You can report adverse events to Amgen's Medical Information Connection™ at 1-800-77-AMGEN. 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 https://www.accessdata.fda.gov/scripts/medwatch/, or mailed to MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787. Both health care professionals and consumers should use Form 3500 (available at the MedWatch website) for reporting adverse events.

A copy of the revised prescribing information for Aranesp® is enclosed. Should you have any questions or require further information regarding the use of Aranesp®, please contact Amgen's Medical Information Connection™ at 1-800-77-AMGEN or online at http://www.amgenmedinfo.com.

Sincerely,

Roy Baynes, MD PhD
Senior Director and Oncology Therapeutic Area Head
Medical Affairs, Amgen Inc

1. Eprex® is manufactured by Ortho Biotech LLC.
2. NeoRecormon® is manufactured by Roche Registration LTD.