*WYETH-AYERST ® GLOBAL PHARMACEUTCIALS*

*150 NORTH RADNOR-CHESTER ROAD • ST. DAVIDS, PA 19087* *Division of American Home Products Corporation*

# Important Pediatric Safety Information

Dear Health Care Professional:

Wyeth-Ayerst brings to your attention an important change to the safety information for NEUMEGA® (oprelvekin) use in the pediatric population. There are no controlled clinical studies that have established a safe and effective dose of NEUMEGA in children. Therefore, the administration of NEUMEGA in children, particularly those <12 years of age, should be restricted to controlled clinical trial settings with closely monitored safety assessments.

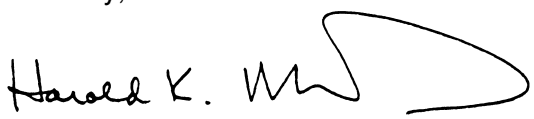
Preliminary data from a safety and pharmacokinetic study in 47 children has identified papilledema as a dose-limiting adverse reaction in the pediatric population. Among the 16 children in this study who received doses of 100 µg/kg/day, four developed papilledema (25%; 95% CI: 7-52%). No subject reported visual abnormalities. In the one patient with adequate follow-up, papilledema was reversible after treatment discontinuation. Although none of the 9 children who received 75 µg/kg/day developed papilledema, given the small number studied the true incidence at this dose may be as high as 33%.

Limited pharmacokinetic data are available for pediatric populations receiving doses of 50 µg/kg/day. Adequate pharmacokinetic data for doses of 50 µg/kg/day were obtained for seven individuals <12 years of age and four individuals >12 and ≤17 years of age. Children (<12 years of age) given doses of 50 µg/kg/day did not achieve effective serum levels. For adolescents (12 to 16 years of age, N = 2) and young adults (≥17 years of age, N = 2) effective serum levels appeared to be achieved.

A copy of the full prescribing information is enclosed. Wyeth-Ayerst is committed to providing you with current product information. The current labeling does not contain the information cited above; once these study data are fully analyzed, the labeling will be changed to provide all currently available information regarding the experience with administration of NEUMEGA in the pediatric population.

We encourage you to help us in monitoring the safety of NEUMEGA by reporting adverse events possibly associated with NEUMEGA to us at 1-800-934-5556. Alternatively, you may report adverse event information directly to FDA's MedWatch reporting system by phone (1-8OO-FDA-1088), facsimile (1-800-FDA-0178), the MedWatch web site 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.

Sincerely,



Harold K. Marder, M.D., FAAP
Senior Vice President and Medical Director