



August 22, 2003

Dear Health Care Professional,

Wyeth wishes to inform you about an update to the prescribing information for Effexor[®] (venlafaxine HCl) Tablets and Effexor[®] XR (venlafaxine HCl) Extended-Release Capsules to reflect important safety information on the use of venlafaxine in children and adolescents. In clinical studies in pediatric patients (ages 6 to 17), efficacy was not established for major depressive disorder (MDD) or generalized anxiety disorder (GAD), and there were increased reports among those patients on Effexor XR, vs. placebo, of hostility and suicide-related adverse events, such as suicidal ideation and self-harm. Effexor and Effexor XR have not been and are not now recommended for use in pediatric patients. We have updated the prescribing information for Effexor and Effexor XR with the following information shown here in italics:

PRECAUTIONS

Usage in Children/ Pediatric Use

Safety and effectiveness in pediatric patients (individuals below 18 years of age) have not been established.

In pediatric clinical trials, there were increased reports of hostility and, especially in Major Depressive Disorder, suicide-related adverse events such as suicidal ideation and self-harm.

The most common adverse events leading to discontinuation in at least 1% of children and adolescents treated with Effexor XR, and at a rate twice that of placebo, were as follows (percentages listed for Effexor XR and placebo, respectively): MDD studies, hostility (2%, <1%) and suicidal ideation (2%, 0%); GAD studies, abnormal/changed behavior (1%, 0%). In these clinical trials there were no suicides.

Venlafaxine is a serotonin and norepinephrine reuptake inhibitor. Effexor XR Extended-Release Capsules are indicated in adults for the treatment of MDD, GAD, and social anxiety disorder (SAD). Effexor Tablets are indicated in adults for the treatment of MDD.

In light of this important information, you should be alert to signs of suicidal ideation in children and adolescent patients prescribed Effexor or Effexor XR. You may need to reassess the benefit-risk balance when treating individual patients with Effexor or Effexor XR. If a decision is made to discontinue a patient from Effexor or Effexor XR, treatment should not be discontinued abruptly, due to

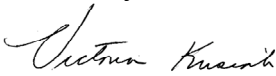
risk of discontinuation symptoms. A gradual reduction in dose under medical supervision is recommended. Please see the prescribing information for additional information with regard to discontinuation.

Wyeth is committed to global surveillance of all its products and to providing you with current product information, and therefore is sending you this letter. Should you have any questions, or wish to report any adverse event associated with Effexor or Effexor XR, please call Wyeth at 1-800-934-5556. In addition, you can send adverse event information directly to Wyeth Global Safety Surveillance and Epidemiology (GSSE) by fax to 610-989-5544 or by mail to GSSE, 500 Arcola Road, Collegeville, PA 19426.

Adverse event information may also be reported to the FDA's MedWatch Reporting System by phone (1-800-FDA-1088), fax (1-800-FDA-0178), via the MedWatch Web site at www.fda.gov/medwatch, or by mail (using postage paid form) to MedWatch, HF-2, 5600 Fisher's Lane, Rockville, MD 20852-9787.

Enclosed is a copy of the revised labeling for Effexor and Effexor XR.

Sincerely,



Victoria Kusiak, M.D.

Vice President, Global Medical Affairs and
North American Medical Director for Wyeth Pharmaceuticals

Enclosures