Wyeth

October 17, 2006

Dear Health Care Provider:

Wyeth would like to update you on changes to the Prescribing Information regarding Effexor XR® (venlafaxine HCl) Extended-Release Capsules and Effexor® (venlafaxine HCl) Tablets.

The Effexor XR Prescribing Information was amended as follows (the Prescribing Information for Effexor was similarly amended):

The OVERDOSAGE/Human Experience section now reads, in part, as follows:

> "In postmarketing experience, overdose with venlafaxine has occurred predominantly in combination with alcohol and/or other drugs. The most commonly reported events in overdosage include tachycardia, changes in level of consciousness (ranging from somnolence to coma), mydriasis, seizures, and vomiting. Electrocardiogram changes (e.g., prolongation of QT interval, bundle branch block, QRS prolongation), ventricular tachycardia, bradycardia, hypotension, rhabdomyolysis, vertigo, liver necrosis, serotonin syndrome, and death have been reported.
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> Published retrospective studies report that venlafaxine overdosage may be associated with an increased risk of fatal outcomes compared to that observed with SSRI antidepressant products, but lower than that for tricyclic antidepressants. Epidemiological studies have shown that venlafaxine-treated patients have a higher pre-existing burden of suicide risk factors than SSRI-treated patients. The extent to which the finding of an increased risk of fatal outcomes can be attributed to the toxicity of venlafaxine in overdosage as opposed to some characteristic(s) of venlafaxine-treated patients is not clear. Prescriptions for Effexor XR should be written for the smallest quantity of capsules consistent with good patient management, in order to reduce the risk of overdose."

Wyeth is committed to providing you with the most current product information available for the management of your patients. In this regard, copies of the full Prescribing Information for both Effexor XR (venlafaxine HCl) and Effexor (venlafaxine HCl) are enclosed for your reference. Additionally, the Prescribing Information for both Effexor XR and Effexor are available to you online at www.wyeth.com/products.

All antidepressants have a potential risk of fatal outcome in overdose. As recommended in the Prescribing Information for all antidepressants, prescriptions should be written for the smallest quantity of drug consistent with good patient management, in order to reduce the risk of overdose. To this end, Wyeth would also like to take this opportunity to remind you that smaller unit-of-use packages of venlafaxine are available to help reduce the risks associated with overdose and to help facilitate more frequent patient-physician contact. Additionally, in recognition of the importance of close interaction between patients taking antidepressants and their treating health care provider, Wyeth, in 2005, introduced an education and support program entitled *Dialogues: Time-to-Talk*™, which was designed to help foster this important communication and contact. If you would like to review these education and support materials, please visit www.mddpatientsupport.com.

If you have any questions regarding Effexor XR or Effexor or wish to report any adverse event associated with Effexor XR or Effexor, please call Wyeth Global Medical Communications at 1-800-934-5556. In addition, you can send adverse event information directly to Wyeth Global Safety Surveillance and Epidemiology and Labeling (GSSEL) by fax to 610-989-5544 or by mail to GSSEL, Wyeth Research, GSSEL-Triage-Dock E, 500 Arcola Road, Collegeville, PA 19426.

Adverse event information may also be reported to the Food and Drug Administration'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 the MedWatch form FDA 3500) to MedWatch, HF-2, 5600 Fishers Lane, Rockville, MD 20852-9787.

Please remember that Effexor XR and Effexor are not indicated for individuals under 18.

IMPORTANT TREATMENT CONSIDERATIONS

Suicidality in Children and Adolescents

Antidepressants increased the risk of suicidal thinking and behavior (suicidality) in short-term studies in children and adolescents with Major Depressive Disorder (MDD) and other psychiatric disorders. Anyone considering the use of EFFEXOR XR® (venlafaxine HCl) or any other antidepressant in a child or adolescent must balance this risk with the clinical need. Patients who are started on therapy should be observed closely for clinical worsening, suicidality, or unusual changes in behavior. Families and caregivers should be advised of the need for close observation and communication with the prescriber. EFFEXOR XR is not approved for use in pediatric patients. (See Warnings and Precautions: Pediatric Use.)

Pooled analyses of short-term (4 to 16 weeks) placebo-controlled trials of 9 antidepressant drugs (SSRIs and others) in children and adolescents with Major Depressive Disorder (MDD), obsessive-compulsive disorder (OCD), or other psychiatric disorders (a total of 24 trials involving over 4,400 patients) have revealed a greater risk of adverse events representing suicidal thinking or behavior (suicidality) during the first few months of treatment in those receiving antidepressants. The average risk of such events in patients receiving antidepressants was 4%, twice the placebo risk of 2%. No suicides occurred in these trials.

Sincerely,

Joseph Camardo, MD
Senior Vice President
Global Medical Affairs

Enclosures – Effexor – Prescribing Information W10402C021
Effexor XR – Prescribing Information W10404C025