VENTAFAXINE HCI EFFEXOR XR® EXTENDE BELSAR GASLAS

FF SUMMARY See package insert for full prescribing information

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 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.

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CONTRAINDICATIONS: Hypersensitivity to venlataxine hydrochloride or to any excipients in the formulation. Concomitant use in patients taking monoamine oxidase inhibitors (MAOIs). WARNINGS: Clinical Worsening and Suicide Risk—Patients with major depressive disorder (MDD), both adult and pediatric, may experience worsening of their depression and/or the emergence of suicidal tibidation and behavior (suicidality) or unusual changes in behavior, whether or not they are taking antidepressant medications, and this risk may persist until significant remission occurs. There has been a long-standing concern that antidepressants may have a role in inducing worsening of depression and the emergence of suicidality in certain patients. Antidepressants increased the risk of suicidal thinking and behavior (suicidality) in short-term suicides in children and adolescents with MDD and other psychiatric disorders. It is unknown whether the suicidality risk in pediatric patients extends to longer-term use i.e., beyond several months. It is also unknown whether the suicidality risk extends to adults. All pediatric patients being treated with antidepressants for any indication should be observed closely for clinical worsening, suicidality, and unusual changes in behavior, especially during the initial few months of a course of drug therapy, or at times of dose changes, either increases or decreases. Anxiety, agitation, panic attacks, insomma, irritability, hostility angressiveness impulsivity, activities of dose changes, either increases or decreases. Anxiety, agitation, panic attacks, insomma, irritability, hostility angressiveness impulsivity, activities of dose changes, either increases or decreases. Anxiety, agi syndrome, seizures, and destth. Erecor XH, should not be used in combination with an inkino of writing at the set of the combination with an inkino in the set of the combination of the set of the s

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Thrombotic Events Often Missed in ICU

BY DOUG BRUNK

San Diego Bureau

SAN DIEGO — Thrombotic events occur frequently in critically ill patients yet may often go unrecognized, Wendy Lim, M.D., reported during a poster session at the annual meeting of the American Society of Hematology.

"We're doing a poor job in actually recognizing these diseases," said Dr. Lim, a clinical research scholar in the department of medicine at McMaster University, Hamilton, Ont. "Because a lot of critically ill patients are endotracheally intubated or sedated, they can't complain of pain in their leg if they have a blood clot, or they can't complain of chest pain if they have a heart attack. We're dependent on patients to express symptoms, and in the case of critically ill patients, we don't have that luxury. We're limited in our abilities."

She and her associates conducted a retrospective chart review of 198 critically ill patients admitted to the medical-surgical intensive care unit at St. Joseph's Hospital in Hamilton, Ont. The patients were part of a prospective cohort study in which twice-daily ultrasound was used to screen for deep vein thrombosis (DVT). Other thrombotic events were diagnosed based on clinical suspicion and confirmed by conventional diagnostic tests.

On admission to the ICU, ultrasound screening revealed DVT in 6 of the 198 patients (3%), but only 3 of the 6 cases (50%) were clinically suspected.

During the ICU stay, 15 patients (7.6%) developed DVT but only 3 of 15 (20%) were clinically suspected.

On admission to the ICU, pulmonary embolism was clinically recognized in 4 patients (2%), while no cases of PE transpired during the ICU stay.

As for arterial events, 4 patients (2%) were admitted with ischemic stroke and 8 (4%) had a stroke in the ICU.

Levels of cardiac troponin I were measured at least once in the first 24 hours of admission in nearly every patient (90%).

On admission to the ICU, 72 patients (36%) had elevated troponin levels and 38 patients (19%) were diagnosed with myocardial infarction. Dr. Lim reported that 29 patients (15%) had elevated troponin levels without typical ischemic ECG changes while 3 patients (1.5%) had elevated troponin levels with a normal ECG.

During the ICU stay, 12 patients (6%) developed elevated troponin levels with associated ischemic ECG changes. Of these patients, only 5 (42%) were diagnosed with MI on admission.

"I think we need to learn a lot more about how to interpret this high frequency of elevated troponin levels in critically ill patients," Dr. Lim commented. "Are all of these patients actually having injuries that are being missed and not being treated appropriately? What does this represent?"

A prospective study is underway to help answer these questions, she said.