

Drugs recently approved or pending approval

CENESTIN

The United States Food and Drug Administration granted marketing approval to Duramed Pharmaceuticals (Cincinnati, OH) for Cenestin (synthetic conjugated estrogens, A). Cenestin is indicated for the treatment of moderate to severe vasomotor symptoms associated with menopause. Drug effectiveness was measured in a randomized, placebo-controlled, multicenter study. Menopausal women ($n = 120$) were randomized to receive Cenestin (0.625 mg) or placebo once daily for 12 weeks. Change in severity of vasomotor symptoms was measured at 4, 8, and 12 weeks. The mean change in reduction of vasomotor symptoms from baseline at all time points was significantly greater for the Cenestin arm compared with the placebo arm. At week 12, the mean change in reduction of vasomotor symptoms was -80.3 for the Cenestin arm and -56.3 for the placebo arm. Cenestin is contraindicated in women with the following conditions: known or suspected pregnancy, undiagnosed abnormal genital bleeding, known or suspected breast cancer, known or suspected estrogen-dependent neoplasia, and active thrombophlebitis or thromboembolic disorders. Adverse events associated with Cenestin may include headache, insomnia, asthenia, paresthesia, flatulence, and breast pain. The recommended starting dose of Cenestin is 0.625 mg with titration up to 1.25 mg; patients should use the lowest dose that controls symptoms.



FERRLECIT

The Food and Drug Administration approved marketing of Ferrlecit (sodium ferric gluconate complex in sucrose injection) by Makoff R&D Laboratories (Marina del Rey, CA). Ferrlecit is indicated for the treatment of iron deficiency anemia in patients undergoing chronic hemodialysis who are receiving supplemental erythropoietin therapy. Safety and efficacy of Ferrlecit were evaluated in two clinical studies. Both studies involved chronic hemodialysis patients with hemoglobin levels below 10 g/dL (or hematocrit at or below 30%) and either serum ferritin below 100 ng/mL or iron saturation below 18%. In the first study, patients were randomized to receive low-dose treatment ($n = 39$) or high-dose treatment ($n = 44$) with Ferrlecit. Patients received eight doses at sequential dialysis sessions over a period of 16 to 17 days. Patients in the low-dose arm received Ferrlecit (62.5 mg of elemental iron) infused over 30 minutes and patients in the high-dose arm received Ferrlecit (125 mg of elemental iron) infused over 60 minutes. A historical control arm ($n = 25$) received

oral iron supplementation for 14 months. Change in hemoglobin levels from baseline was the primary endpoint of the study; observation period was 40 days. Mean change in hemoglobin from baseline in the high-dose arm was 1.1 g/dL compared with 0.3 g/dL in the low-dose arm and 0.4 g/dL in the historical control arm. In the second study, patients ($n = 38$) treated with either dose of Ferrlecit (62.5 or 125 mg of elemental iron) were compared with a historical control arm ($n = 25$). Change in hemoglobin levels from baseline was the primary endpoint; observation lasted for 50 days. Mean change in hemoglobin levels was 1.3 g/dL in the Ferrlecit arm compared with 0.4 g/dL in the control arm. Potential side effects associated with Ferrlecit include malaise, nausea, dizziness, and abdominal pain. The recommended dosage is 10 mL of Ferrlecit (125 mg of elemental iron) diluted in 100 mL of 0.9% sodium chloride for injection, administered by intravenous infusion over 1 hour.

EFFEXOR XR

American Home Products (Madison, NJ) received approval to market Effexor XR (venlafaxine hydrochloride) for a new indication. Previously indicated for the treatment of depression, Effexor XR is now indicated for the treatment of generalized anxiety disorder (GAD) as defined by the *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV)*.

Effectiveness of Effexor XR was measured in two 8-week, placebo-controlled studies involving outpatients who met the *DSM-IV* criteria for GAD. In the first study, patients received either 75, 150, or 225 mg/day of Effexor XR or placebo. Based on the Hamilton Rating Scale for Anxiety (HAM-A) and the Clinical Global Impressions (CGI) scale, patients in all three Effexor XR arms showed more improvement than the placebo arm; the 225 mg/day arm was the most consistently improved. In the second study, patients received 75 or 150 mg/day of Effexor XR or placebo. Again, the Effexor XR arms showed more improvement than the placebo arm on the HAM-A and CGI scales. Effexor XR is contraindicated in patients who are also taking monoamine oxidase inhibitors. Possible adverse events associated with Effexor XR include sexual dysfunction, nausea, dry mouth, and insomnia. The recommended starting dose for the treatment of GAD is 75 mg/day administered as a single dose.

Compiled from press reports and pharmaceutical company press releases. For more information, contact Deidre Yoder, Hospital Physician, 125 Strafford Avenue, Suite 220, Wayne, PA 19087-3391.