Generic Name:
Peginesatide
Trade Name:
Omontys
Company:
Affymax
Notes:

FDA announced the approval of peginesatide for the management of anemia in adult patients who have chronic kidney disease (CKD) and are receiving dialysis. This new erythropoiesis-stimulating agent (ESA) is a once-monthly injection, minimizing the need for more frequent injections.

Approval was based on data from two randomized, active-controlled, open-label, multicenter clinical trials involving 1,608 patients with CKD who were on dialysis. The trials randomized patients with hemoglobin levels initially stabilized by ESA to receive either peginesatide once monthly or to continue their current ESA (epoetin) treatment. Results showed peginesatide to be as safe and effective as epoetin in maintaining hemoglobin levels within the studies? prespecified range of 10?12 g/dL.

The most common adverse events, observed in 10% or more of patients receiving dialysis who were treated with peginesatide, were diarrhea, vomiting, hypertension, and arthralgias. As with other ESAs, peginesatide has numerous safety considerations and was approved with a Risk Evaluation and Mitigation Strategy.

Medication Monitor Categories:
New Drug Approvals
Use:

Treatment of anemia in patients on dialysis