Supplemental Approvals

Generic Name (Trade Nameâ€"Company)

Uses/Notes

June 8, 2018

Methoxy polyethylene glycol-epoetin beta

(Mircera—Vifor Pharma)

Approval expanded for anemia associated with CKD in pediatric patients on dialysis

FDA approved methoxy polyethylene glycol-epoetin beta for the treatment of pediatric patients aged 5 to 17 years on hemodialysis who are converting from another erythropoietin-stimulating agent (ESA) after their hemoglobin level was stabilized with an ESA.

Approval was based on data from an open-label, multiple dose, multicenter, dose-finding trial in 64 pediatric patients (aged 5–17 y) with chronic kidney disease (CKD) on hemodialysis and had stable hemoglobin (Hb) levels while previously receiving another ESA (epoetin alfa/beta or darbepoetin alfa). Patients were administered methoxy polyethylene glycol-epoetin beta intravenously once every 4 weeks for 20 weeks. After the first administration, dosage adjustments were permitted to maintain target Hb levels.

Efficacy was based on maintaining Hb levels within target levels in the above clinical trial, and also from extrapolation from trials the agent in adult patients with CKD. The safety findings observed in pediatric patients were consistent with those previously reported in adults.

For conversion from another ESA, Mircera is dosed intravenously once every 4 weeks based on total weekly epoetin alfa or darbepoetin alfa dose at time of conversion. Full prescribing information is available at Mircera PI.

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