

[New Drug Approvals](#)

Generic Name (Trade Name) Company

December 11, 2018

Fish oil triglycerides injectable emulsion (Omegaven—Fresenius Kabi)

I.V. lipid emulsion approved for pediatric patients with parenteral nutrition-associated cholestasis

Uses/Notes

Fresenius Kabi announced that [fish oil triglycerides injectable emulsion](#), approved under the trade name Omegaven, is now commercially available in the United States. This novel lipid had previously been available only for compassionate use in the United States.

Omegaven is an I.V. lipid emulsion that provides calories and fatty acids for pediatric patients with parenteral nutrition-associated cholestasis, or PNAC. It is the first and only FDA-approved fish oil lipid emulsion for this condition.

The product is available as a 5 g/50 mL and 10 g/100 mL (0.1 g/mL) injectable emulsion in a single-dose bottle.

Cholestasis is a condition in which bile is not released from the liver. PNAC may occur following long-term parenteral nutrition administration in pediatric patients with temporary or permanent intestinal failure. Development of PNAC is associated with increased morbidity and mortality and can progress to liver fibrosis, hepatic failure, and death.

In clinical trials, the most common adverse drug reactions (>15%) were vomiting, agitation, bradycardia, apnea, and viral infection.

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