

(<http://aphanet.org>)

[Home](#) > I.V. lipid emulsion approved for pediatric patients with parenteral nutrition-associated cholestasis

Generic Name:

Fish oil triglycerides injectable emulsion

Trade Name:

Omegaven

Company:

Fresenius Kabi

Notes:

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

Omegeaven 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.

Medication Monitor Categories:

[New Drug Approvals](#)

Source URL: <http://aphanet.org/new-drug-approvals/iv-lipid-emulsion-approved-pediatric-patients-parenteral-nutrition-associated>