Table 1: Recommended Pediatric Dosage and Infusion Rate

- Monitor triglyceride levels during treatment [see Warnings and Precautions (5.4, 5.6) and Overdosage (10)].
- Start infusion of admixtures containing Omegaven immediately.
- Do not add Omegaven directly to the empty PN container; hang the bottle using the attached hanger and start infusion.
- Use a vented infusion set when Omegaven is infused from the bottle.
- Protect the admixed PN solution from light. (2.2)

Dosing Considerations

- For information on infusion rate when initiating dosing and in patients with severe disorders of lipid metabolism characterized by hypertriglyceridemia (e.g., renal disease, other drugs).
- Twelve (6%) Omegaven-treated patients were listed for liver transplantation.
- Neutropenia: 13 (7)
- Erythema: 23 (12)
- Viral Infection: 30 (16)
- Bradycardia: 66 (35)
- Agitation: 67 (35)

To prevent these complications, closely monitor severely malnourished nutrition (PN)-dependent patients [see Clinical Studies (14)].

Medication guide:

- Medications should be prescribed on the basis of the patient's needs in order to prevent complications.
- Medications should not be prescribed on the basis of their cost, availability, or other factors that may influence the patient's choice of medication.

Full prescribing information:

- Sections or subsections omitted from the full prescribing information are not included.
- Omegaven contains Vitamin K that may counteract anticoagulant effect.
- Routine monitoring is recommended, including monitoring for essential fatty acid deficiency.
- Omegaven contains no more than 25 mcg/L of aluminum. Aluminum levels should be assessed before and during treatment.
- Monitoring and Laboratory Tests:  Routine laboratory monitoring is recommended.
- Hypersensitivity Reactions:  Monitor for signs or symptoms. Discontinue the infusion if reaction occurs. (5.2)
- Antiplatelet Agents and Anticoagulants:  Prolonged bleeding time has been observed in patients who received PN with Omegaven as the sole lipid source; he had no other bleeding disorder.
- Eleven (6%) Omegaven-treated patients experienced bleeding.
- Median hemoglobin levels and platelet counts for Omegaven-treated patients were 11.0 g/dL and 229,000 cells/µL, respectively, at baseline and 12.1 g/dL and 262,000 cells/µL, respectively, after treatment.
The fish oil included in Omegaven is a triglyceride mixture consisting of tocopherol, 0.3 mg sodium oleate, water for injection, and sodium 0.012 g egg phospholipids, 0.025 g glycerin, 0.15 to 0.3 mg dl-alpha-homogenous emulsion for intravenous infusion as a supply of calories (5.1). 

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility 

Point, the average was used. Numbers at the top of plots represent the number of patients at each Error bars represent ± 1 standard deviation (SD).

Weeks of Omegaven Infusion in Pediatric Patients with PNAC 

Fatty acids serve as an important substrate for energy production. The most common mechanism of action for energy production derived bioactive molecules (such as prostaglandins), and as regulators of gene expression.

The mean content of the two major fatty acid components in 50 mL are 0.16 g, 0.07 g, and 0.13 g, are 1.0 g EPA (range: 0.6 to 1.5 g) and 0.96 g DHA (range: 0.7 to 1.2 g).

8.2 Lactation 

No data are available regarding the presence of fish oil triglycerides in human milk. While it is not known whether Omegaven is absorbed by the breastfed infant, use of Omegaven during breastfeeding is not recommended due to the potential for serious adverse reactions in the breastfed infant. The potential for Omegaven to impair milk production in breastfeeding women is unknown. Lactating women receiving oral or the effects on milk production. Lactating women receiving oral

There are no available data on Omegaven use in pregnant women to evaluate the effect of Omegaven on the fetus. Omegaven use during pregnancy should be avoided as it is not known whether it can cause fetal harm when administered to a pregnant woman. If Omegaven use is essential for the mother during pregnancy, the possibility of using a lower dose of Omegaven should be considered.

17 PATIENT COUNSELING INFORMATION 

Inform caregivers that prolonged PN administration in patients with infection. If Omegaven is infused at home, instruct caregivers to ensure infusion within 24 hours after removal from storage [see Dosage and Administration (2.3), Adverse Reactions (6.1)].

2.2 Short term infusion. No data are available regarding the presence of fish oil triglycerides in human milk. While it is not known whether Omegaven is absorbed by the breastfed infant, use of Omegaven during breastfeeding is not recommended due to the potential for serious adverse reactions in the breastfed infant. The potential for Omegaven to impair milk production in breastfeeding women is unknown. Lactating women receiving oral or the effects on milk production. Lactating women receiving oral

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