

Omegaven formulation

Newborn use only

2023

Alert	Omegaven should only be used for treatment in infants with moderate to severe intestinal failure associated liver disease (IFALD), previously known as parenteral nutrition associated cholestasis (PNAC). In Australia, omegaven ordering requires SAS form. (Refer to ordering section)																
Indication	Treatment of moderate to severe IFALD – Suggested conjugated bilirubin >68 µmol/L (4 mg/dL) (ANMF consensus)																
Action	Omegaven compounded formulation provides fatty acids, non-protein energy, fat soluble and water-soluble vitamins. Omegaven is 100% fish oil and is available as 10% emulsion. Omegaven is a rich source of docosahexaenoic acid (DHA), eicosapentaenoic acid (EPA) and vitamin E (alpha-tocopherol). It contains negligible amount of phytosterols.																
Drug type	Lipid emulsion.																
Trade name	Omegaven compounded formulation – supplied by Fresenius-Kabi.																
Presentation	Omegaven compounded formulation prepared by Fresenius-Kabi: ² (1) 50 mL syringe – Code: FKSOM50V (2) 150 mL bag - Code: FKCOM150V																
	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: left;">Contents</th> <th style="text-align: center;">50 mL syringe for ≤1 Kg</th> <th style="text-align: center;">150 mL bag for >1 Kg</th> </tr> </thead> <tbody> <tr> <td>Omegaven 10%</td> <td style="text-align: center;">36 mL</td> <td style="text-align: center;">108 mL</td> </tr> <tr> <td>Soluvit N</td> <td style="text-align: center;">2.8 mL</td> <td style="text-align: center;">8.4 mL</td> </tr> <tr> <td>Vitalipid N Infant 10%</td> <td style="text-align: center;">11.2 mL</td> <td style="text-align: center;">33.6 mL</td> </tr> <tr> <td>Total lipid</td> <td style="text-align: center;">5g (3.9g from omegaven+1.1g from vitalipid)</td> <td style="text-align: center;">15g (11.7g from omegaven+3.3g from vitalipid)</td> </tr> </tbody> </table>		Contents	50 mL syringe for ≤1 Kg	150 mL bag for >1 Kg	Omegaven 10%	36 mL	108 mL	Soluvit N	2.8 mL	8.4 mL	Vitalipid N Infant 10%	11.2 mL	33.6 mL	Total lipid	5g (3.9g from omegaven+1.1g from vitalipid)	15g (11.7g from omegaven+3.3g from vitalipid)
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Dose	<p>1 g/kg/day (Refer to practice points section)</p> <p>1 g/kg/day equates to the volumes of the compounded formulation as below:</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: left;">Lipid, g/kg/day</th> <th style="text-align: center;">Omegaven formulation, mL/kg/day</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">1 g/kg/day</td> <td style="text-align: center;">10 mL/kg/day</td> </tr> </tbody> </table> <p>Duration >4 weeks: Prolonged therapy with omegaven alone can result in essential fatty acid (EFA) deficiency. Seek the advice of the NICU dietitian and/or Paediatric gastroenterology team for omegaven therapy beyond 4 weeks (ANMF consensus)</p> <p>In Australia, mixed fish oil lipid emulsion (SMOFlipid) is the standard Intravenous lipid emulsion (ILE). Clinical benefit of Omegaven over SMOFlipid in PNAC is unclear. There is also concern about EFA deficiency with pure omegaven alone. Until the evidence is clear, clinicians may choose other options including (1) replacing a portion of SMOFlipid with omegaven in infants with PNAC/IFALD, or (2) administering SMOFlipid 2-3 days a week and omegaven other days.</p>		Lipid, g/kg/day	Omegaven formulation, mL/kg/day	1 g/kg/day	10 mL/kg/day											
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1 g/kg/day	10 mL/kg/day																
Ordering	<ul style="list-style-type: none"> • All orders for compounded Omegaven formulations in Australia will require an SAS form, as this is not a TGA registered product in Australia. SAS form should accompany the order form to avoid delay. • Please obtain any required approval from the hospital Drug and Therapeutic Committee and complete a valid Category A or Category B SAS form (whichever is most appropriate for the current patient). • NICU team/pharmacist (as per your facility arrangement) to place an order directly to Fresenius Kabi. Please send the completed order and SAS forms via email to: TPN.Sydney@fresenius-kabi.com or Fax: 1300 304 384 • Request to send the order by 10 am, to ensure orders will be delivered the next business day for Metro Sydney or 2 business days later for regional NSW and other states across Australia. • If you have any questions regarding the ordering process, please contact Fresenius Kabi Customer service directly on 1300 732 001. 																
Dose adjustment	In most cases omegaven does not need to be withheld in response to high triglyceride levels. ¹⁰⁽¹²⁾																
Maximum dose	1.5 g/kg/day ³																
Route	IV																
Preparation	No preparation is required for compounded formulation. Syringes and bags are supplied in light protected amber coloured foils/syringes/tubings.																

Administration	Continuous IV infusion over 24 hours. DAILY volume may also be administered over 20 hours. Maximum hang time at room temperature: 48 hours.
Monitoring	IV site for extravasation. Monitor EFA (Essential Fatty Acid) profile if the patient has signs/symptoms of EFAD (EFA Deficiency), receiving omegaven for a long duration or failing to thrive. Other laboratory monitoring as part of complete parenteral nutrition – These include blood glucose, electrolytes, liver and renal function, triglyceride, full blood count.
Contraindications	Hypersensitivity to fish-, egg-, soya- or peanut protein or to any of the active substances or excipients. Severe hyperlipidemia. Severe liver insufficiency. Severe blood coagulation disorders. Severe renal insufficiency without access to hemofiltration or dialysis. Acute shock. General contraindications to infusion therapy: acute pulmonary oedema, hyperhydration, decompensated cardiac insufficiency. Unstable conditions (e.g. severe metabolic acidosis, severe sepsis and hypotonic dehydration). Drug induced liver injury (e.g. paracetamol overdose) ¹⁰
Precautions	Hepatic impairment Impaired lipid metabolism which can occur in sepsis, renal or hepatic impairment.
Drug interactions	The addition of medications to the compounded formulation should be avoided.
Adverse reactions	Hypertriglyceridemia - uncommon Accidental overload: Fat overload syndrome that is seen with soy-oil based ILE (e.g. Intralipid) has not been reported with omegaven. However, if there is an accidental overdosage: stop the infusion, check serum triglyceride level 4 hours later; if <4.5 mmol/L (<400 mg/dL), resume infusion. If still elevated, hold another 4 hours and recheck serum triglycerides. ⁹ Bleeding – No consistent evidence of association between bleeding and fish oil ILE.
Compatibility	Can be co-administered with PN. No other compatibility information is currently available. Do not infuse with other medications.
Incompatibility	Must not be mixed with other medications.
Stability	50 mL syringe: 13 days at 2-8°C; 150 mL bag: 12 days at 2-8°C
Storage	Compounded formulations are to be stored in refrigerator once they arrive the NICU.
Evidence	<p>Background</p> <p>Essential fatty acids (EFA) are not synthesised by the body and needs to be provided by dietary sources. Omega-6 and omega-3 are the two major families of EFA. Linoleic acid and arachidonic acids are examples of omega-6 polyunsaturated fatty acids (PUFAs). α-linolenic acid, Eicosapentaenoic acid (EPA), and docosahexaenoic acid (DHA) are examples of omega-3 PUFAs. Vegetable oils are a major source of linoleic acid. Arachidonic acid and DHA are critical for growth, brain, and eye development. Intravenous lipid emulsions (ILEs) are made up of triglycerides (TGs) and phospholipids. TGs are composed of 3 FAs attached to a glycerol backbone. Phospholipids act as an emulsifier so that TGs in ILEs can exist in an aqueous solution. Omegaven contains 13-26 g of EPA & 14-27 g of DHA per Litre and SMOFLipid contains 2-7 g of EPA & DHA each per L (Information provided by the manufacturer on 23 November 2023)</p> <p>Efficacy</p> <p><u>Intestinal failure Associated Liver Disease (IFALD)</u></p> <p>Clinical signs of early IFALD are non-specific and generally defined on biochemical terms. Early IFALD is defined mainly in relation to bilirubin.¹ Isolated hyperbilirubinaemia (>20 μmol/L) should be considered as a “red flag.” Total bilirubin persistently >100 μmol/L for at least 2 to 4 weeks is a sign of marked liver injury, predicting progression to severe IFALD.¹ Children with IF but without IFALD frequently have an isolated increase in transaminases (alanine transaminase and aspartate aminotransferase), or a moderate increase in gamma-glutamyl transferase (usually <150 IU/L). Its pathogenesis is multifactorial and phytosterols in ILE, high concentrations of the n-6 PUFAs (eg, LA) and low concentrations of the n-3 PUFAs (eg, ALA) are thought to be major contributory factors. The patient-related risk factors include prematurity, intrauterine growth restriction, lack of enteral feeds and sepsis.¹ Soy Oil ILE (e.g. Intralipid) has high concentration of phytosterols, high omega-6:omega-3 ratio contributing to cholestasis. Vitamin E (α – tocopherol) is an anti-oxidant and scavenges free radicals. Omega-3 fatty acids are anti-inflammatory. Fish-oil contains a negligible amount of phytosterols, a low omega:6-omega:3 fatty acid ratio, and a high α-tocopherol concentration.</p>

Lipid emulsions (LE) and cholestasis

A Cochrane systematic review conducted by Kapoor et al (2019)¹⁴ compared the safety and efficacy of all LE for parenteral nutrition (PN) in preterm infants <37 weeks' gestation including infants with surgical conditions or parenteral nutrition-associated liver disease. They included 29 studies (n = 2037).¹⁴ The LEs were classified into 3 broad groups- 1) all fish oil containing LE including pure fish oil LE 2) conventional LE (soybean LE) and 3) alternative LE. The review included 2 studies found only 2 studies,^{3,15} described in detail below. The review concluded that in preterm infants with surgical conditions or cholestasis, there is currently insufficient evidence from randomised studies to determine with any certainty if pure fish oil LEs (e.g. omegaven) offer advantage in prevention or resolution of cholestasis or in any other clinical outcome.

Omegaven for treatment of IFALD

Lam et al conducted a randomised controlled trial comparing the effect of omegaven (1.5 g/kg/day, n=9) to Intralipid (1.5 g/kg/day, n=7) on reversal of cholestasis in infants with IFALD.³ Although the reversal of cholestasis in 4 months was similar, intralipid group's conjugated bilirubin (CB) increased at a significant rate (0.79mg/dL per week, $P < 0.01$), whereas the CB in omegaven group was nonsignificant and negligible (0.04 mg/dL per week. $P = 0.9$). The weekly weight gain was higher in omegaven group compared to intralipid group (128 g/week vs 83 g/week, $p = 0.02$). The median duration of omegaven was 40 days (Inter-quartile range, 18-90 days). This trial was terminated early because parents became unwilling to consent with increased public awareness of fish oil LE.

Nehra et al¹⁵ conducted a randomised controlled trial to determine if the administration of a fish oil ILE (omegaven) was safe and effective in reducing the incidence of cholestasis in surgical neonates expected to be PN dependent for 3 weeks compared with soybean oil ILE (intralipid). The eligible infants (n=19) were <3 months of age and direct bilirubin was < 17 $\mu\text{mol/L}$. Primary outcomes was the incidence of cholestasis, defined as a serum direct bilirubin > 34 $\mu\text{mol/L}$ for 2 consecutive weeks. The median duration of omegaven was 36 days (Inter-quartile range, 29,76). The incidence of cholestasis among enrolled patients was significantly lower than expected, resulting in early study termination and an inability to assess for differences in the incidence of cholestasis. Nutritional assessment and neurodevelopmental follow up was conducted. The omegaven group had no growth impairment, coagulopathy, infectious complications, hypertriglyceridemia, or adverse neurodevelopmental outcomes.¹⁵

Puder et al,⁴ in an open label trial with historical cohort as the control group, studied the outcomes of 42 children with PNAC treated with omegaven (1 g/kg/d). Safety and efficacy outcomes were compared with a historical cohort of 49 children with PNAC who had received Intralipid (1-4 g/kg/day). Primary endpoint was time to reversal of cholestasis. Among patients who did not die nor were transplanted while on PN, 19 of 38 (50%) reversed cholestasis in omegaven cohort and only 2 of 36 (5.6%) reversed in intralipid ($P = < 0.0001$). The group that transitioned to omegaven had a significantly lower rate of mortality and/or transplantation (9.5%) than did the group that continued to receive PN and intralipid (34.7%; $P = 0.005$). The median time to PN cessation was 20 weeks (IQR 9-29 weeks) in omegaven cohort. Omegaven was not associated with hypertriglyceridemia, coagulopathy, or essential fatty acid deficiency.

Premkumar et al,⁵ reported their 5-year experience of omegaven in PNAC children <6mo of age. A total of 97 infants were enrolled, 83 infants (86%) survived with resolution of cholestasis and 14 (14%) died. Non-survivors were more premature (GA, 26wk) and took longer to resolve cholestasis. Infants were classified into 3 groups depending on their conjugated bilirubin (CB) at the time of omegaven initiation- Group A (CB 34-85 $\mu\text{mol/L}$), Group B (CB 85-170 $\mu\text{mol/L}$), Group C (CB >170 $\mu\text{mol/L}$). The median CB at the initiation of omegaven was 82 $\mu\text{mol/L}$. Cholestasis resolution occurred during the median period of omegaven of 40 days (range 3-158 days). Gestational age at birth correlated inversely with CB at the beginning of omegaven and peak CB. Infants with an initial CB >170 $\mu\text{mol/L}$ had a higher mortality rate than infants with an initial CB <85 $\mu\text{mol/L}$ (35% vs. 6%; $P < 0.05$).

Wang et al,⁶ reported 5-year follow up of 48 IFALD infants. Children with IFALD were treated for 6 months with omegaven and PN dependent infants were then restarted soybean oil ILE (SOLE). Cholestasis resolution occurred in 71% after 6 months of omegaven. 27 infants were recommenced on SOLE. Cholestasis recurred in 26% and 6% of them needed liver transplant. Due to this experience, authors argued for long-term fish oil ILE therapy to prevent end-stage liver disease in IFALD infants.

A retrospective study by Ramiro-Cortijo et al,⁷ reported cholestasis resolution in infants with omegaven as a rescue therapy.⁷ All infants were initially treated with mixed oil ILE (SMOF 3g/kg/d). Omegaven at 1g/kg/d was used as a rescue measure when infants developed cholestasis. This study included 38 neonates with cholestasis: (1) 28 infants with intestinal disease and with CB >34 $\mu\text{mol/L}$ and (2) 10 infants without intestinal disease, but with CB >68 $\mu\text{mol/L}$. Age at diagnosis of cholestasis was 15 days. Omegaven was used for median 29 days (Interquartile range, 31-69 days). Cholestasis resolution occurred in 74%

infants. High mortality was noted in infants who had no resolution of cholestasis compared to infants with cholestasis resolution (80% vs 3.6%, $p < 0.001$).

A retrospective study by Anzueto Guerra¹⁶ examined the effects of a combination ILE (soybean oil-based + fish oil-based lipid emulsions) compared to omegaven as monotherapy on the lipid and fatty acid profiles and clinical outcomes of 42 premature infants requiring prolonged PN. Infants were diagnosed with short bowel syndrome or severe intestinal dysmotility. They were divided into 2 groups- The fish oil group (omegaven, $n=28$) had established IFALD with direct bilirubin $>68 \mu\text{mol/L}$ and received Omegaven 1 g/kg/d. The combination ILE group ($n=14$) infants were at high risk of developing IFALD with direct bilirubin $>17 \mu\text{mol/L}$ but $<68 \mu\text{mol/L}$ and received soy oil LE 1-2 g/kg/d + omegaven 1g/kg/d. If direct bilirubin increased more than $68 \mu\text{mol/L}$, soy oil LE was discontinued and omegaven was continued. Omegaven was continued until cholestasis resolution or weaned off PN. The mean duration of fish oil therapy was 95 ± 54 days. Plasma concentrations of ω -6 fatty acids decreased over time in both the groups while the concentrations of most ω -3 fatty acids (eicosapentaenoic acid and docosahexaenoic acid) were significantly increased over time in the FishLE+SoyLE group whereas they did not change in the FishLE alone group. However, serum concentrations of almost all fatty acids were similar between groups at the end of the study period. No differences in growth parameters and neurodevelopmental outcomes at 6, 12, 18, and 24 months of age were noted.¹⁶

Safety

Essential Fatty acid deficiency (EFAD): Omegaven has negligible amounts of linoleic and α -linolenic acid, raising theoretical concerns about the development of essential fatty acid deficiency (EFAD) in patients on long-term therapy with omegaven alone. However, Gura's study revealed only a single case of EFAD, defined by a triene: tetraene ratio > 0.2 ; as well as no significant differences in other safety measures when compared to historical controls receiving soybean-oil based emulsions.⁸

Fat overload syndrome)/hypertriglyceridemia: This is a known complication with rapid infusions of soybean oil based ILE (e.g. Intralipid). However, no such complication was reported with omegaven to date. A case series described the outcomes of 6 patients in whom omegaven was infused at rates as high as 5 g/kg/hour accidentally (range, 0.2–5 g/kg/hour). There was no evidence of fat overload syndrome.⁹ Transient elevations in serum triglyceride levels were observed, but promptly returned to acceptable levels. Fish oil ILE appears to be cleared rapidly from the intravascular space. In animal models, regardless of the oil source, most ILE clearance from the blood occurs within the first 2 minutes of the infusion.¹⁰

Accidental overdose: Omegaven does not remain in the systemic circulation long enough to predispose patients to complications associated with the rapid infusion of soybean oil ILE. However, in the event of a rapid infusion of fish oil ILE, patients should still be considered at risk for hypertriglyceridemia. Omegaven should be immediately stopped, and a serum triglyceride level should be checked 4 hours later. In general, if the triglyceride levels are $<400 \text{ mg/dL}$ in neonates and infants, infusion can be resumed.¹¹

Bleeding: There is no consistent evidence to suggest any association with fish oil ILE and bleeding from platelet dysfunction.¹¹

Practice points

Composition of common intravenous lipid emulsions¹

	Intralipid 20%	SMOFlipid 20%	Omegaven 10%
Oil source (%)			
Soy oil	100	30	0
MCT oil	0	30	0
Olive oil	0	25	0
Fish oil	0	15	100
Phytosterols (mg/L)	422	124	0-4
α – tocopherol (mg/L)	32	163-225	150-300

*Different studies reported different amounts.^{1,12,13,17}

Estimated fat and vitamin intakes in **preterm** neonates with omegaven formulation

Unit/kg/day	ESPGHAN 2018	1 g/kg/day	2 g/kg/day
Fat, g	3-4	1	2
Vit A, IU	700-1500	515.2	1030.4
Vit D, IU	80-400	89.60	179.2
Vit E, IU	2.8-3.5	1.57	3.1
Vit K, μg	10	44.80	89.6
Thiamine, μg	350-500	173.60	347.2

Riboflavin, µg	150-200	274.40	548.8
Niacin, mg	4.0-6.8	2.24	4.5
Pyridoxine, µg	150-200	274.40	548.8
Folate, µg	56	22.40	44.8
Vit B12, µg	0.3	0.28	0.6
Pantothenate, mg	2.5	0.92	1.8
Biotin, µg	5-8	3.36	6.7
Vit C, mg	15-25	6.33	12.7

Estimated vitamin intakes in **term** neonates with omegaven formulation

Unit/kg/day	ESPGHAN 2018	1 g/kg/day	2 g/kg/day
Fat, g		1	2
Vit A, IU	462-989	515.2	1030.4
Vit D, IU	40-150	89.60	179.2
Vit E, IU	2.8-3.5	1.57	3.1
Vit K, µg	10	44.80	89.6
Thiamine, µg	350-500	173.60	347.2
Riboflavin, µg	150-200	274.40	548.8
Niacin, mg	4.0-6.8	2.24	4.5
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Biotin, µg	5-8	3.36	6.7
Vit C, mg	15-25	6.33	12.7

Caution: The prolonged use of 1g/kg/d of omegaven therapy may lead to significant under dosage of fat and water-soluble vitamins and the dietetics team should consider its monitoring and appropriate supplementation.

References

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