Baxter

Finomel

PARENTERAL NUTRITION

MORE

~~LESS~~ IS

MORE

Finomel - containing a four-oil lipid emulsion with more fish oil than in any other triple-chamber bag.[1-3]

Finomel - triple-chamber bag offering a more balanced lipid profile

FISH OIL
20%
The most fish oil available in a triple-chamber bag[1-3]

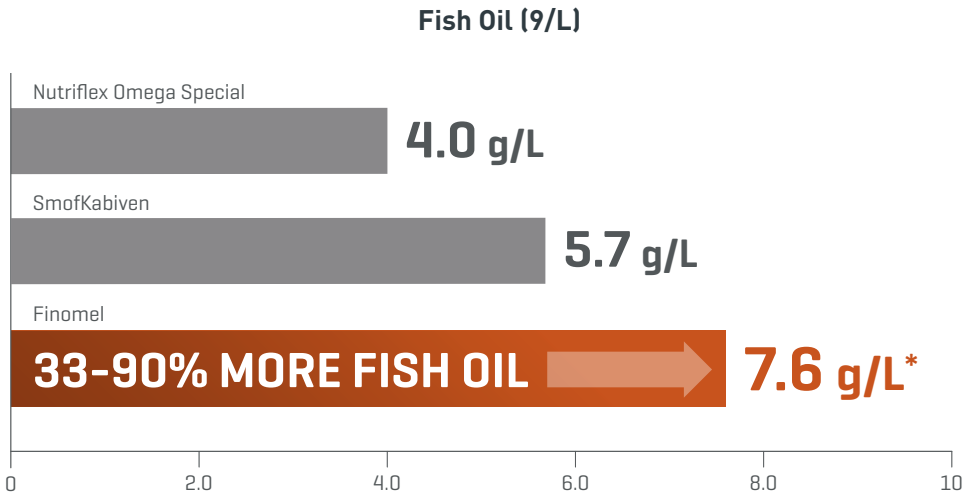
OLIVE OIL
25%
May preserve **immune function**[1,4-9]

MEDIUM-CHAIN TRIGLYCERIDES (MCTs)
25%
Fewer MCTs than in other triple-chamber bags[1-3]

SOYBEAN OIL
30%
To help **prevent essential fatty acid (EFA) deficiency**[1]

MORE fish oil than in any other triple-chamber bag[1-3]

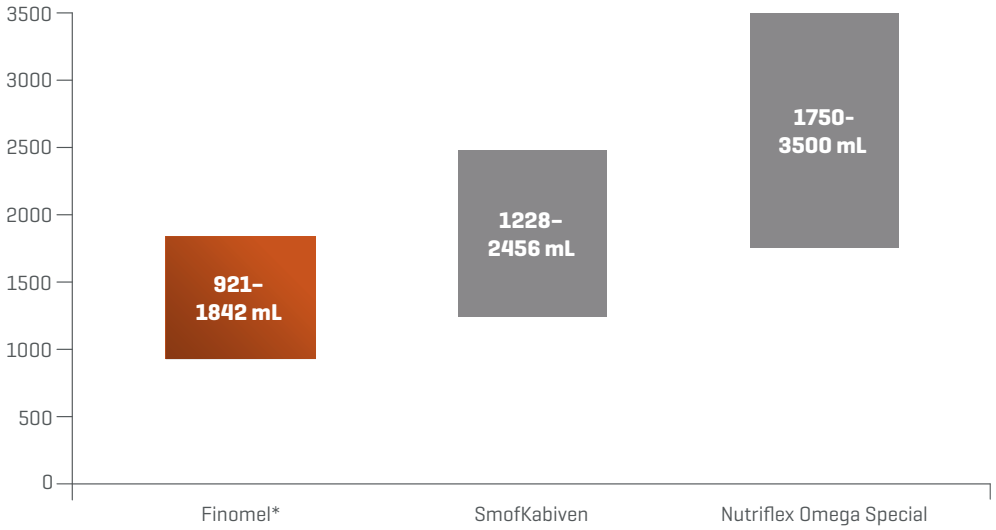
Finomel has 7.6 g/L of fish oil rich in Omega-3.



Fish oil g/L included in Nutriflex Omega Special, SmofKabiven, and Finomel
*Finomel has 7.6 g/L and Finomel Peri has 5.6 g/L of fish oil rich in Omega-3

Finomel provides higher fish oil intake with a lower fluid volume

Volume needed to provide a fish oil dose of 0.1–0.2 g/kg/day for a 70 kg adult[1-3,10]



Compared with SmofKabiven and Nutriflex Omega Special, a lower volume of Finomel is needed to meet the ESPEN-recommended fish oil dose of 0.1–0.2 g/kg/day[1-3,10]

Finomel triple-chamber bags are offered in two convenient options

	FINOMEL PERI** (with electrolytes)		**FINOMEL** (with electrolytes)	
Volume (mL)	**1450**	**2020**	**1435**	**1820**
Total calories approx. (kcal)	**1003**	**1398**	**1567**	**1988**
Amino acids/protein (g)	**46**	**64**	**73**	**92**
Nitrogen (g)	7.5	10.5	12	15.3
Glucose calories (kcal)†	431	600	755	958
Lipid calories (kcal)‡	389	544	521	661
Non-protein calories (kcal)/ nitrogen ratio (g)	109	109	106	106
Sodium (mmol)	36.6	50.9	58.3	73.9
Potassium (mmol)	27.5	38.2	43.8	55.5
Magnesium (mmol)	4.6	6.4	7.3	9.3
Calcium (mmol)	2.3	3.2	3.7	4.7
Phosphorus (mmol)	8.8/11.9§	12.3/16.6§	14.1/18.3§	17.9/23.1§
Acetate (mmol)	65.9	91.7	105	133
Chloride (mmol)	50.2	69.9	80.1	102
Sulfate (mmol)	4.6	6.4	7.4	9.3
Zinc (mmol)	0.04	0.05	0.06	0.07
Osmolarity (approx.) (mOsm/L)	850	850	1440	1440
Product code	**1101323**	**1101324**	**1101320**	**1101321**

*Finomel has 7.6 g/L and Finomel Peri has 5.6 g/L of fish oil rich in Omega-3 **Finomel Peri can be delivered peripherally †As sum of glucose and glycerol content in g x 4 kcal/g ‡As sum of oil and phospholipids content in g x 9 kcal/g §Without phosphorus from lipid emulsion/with phosphorus from lipid emulsion

Finomel / Finomel Peri emulsion for infusion

Name and composition: Finomel / Finomel Peri is a 3-compartment plastic bag containing sterile, non-pyrogenic combination of glucose solution, a 10% amino acid solution with electrolytes, and a 20% lipid emulsion. Before reconstitution the glucose and amino acid solutions are clear and colourless to slightly yellow and free from particles. The lipid emulsion is white and homogeneous. After reconstitution, the appearance of the product is a white emulsion.

Active substance	Finomel			Finomel Peri		
	1085 ml	1435 ml	1820 ml	1085 ml	1450 ml	2020 ml
Fish oil, rich in omega-3-acids	8.24 g	10.92 g	13.84 g	6.12 g	8.16 g	11.40 g
Olive oil, refined	10.30 g	13.65 g	17.30 g	7.65 g	10.20 g	14.25 g
Soya-bean oil, refined	12.36 g	16.38 g	20.76 g	9.18 g	12.24 g	17.10 g
Medium chain triglycerides	10.30 g	13.65 g	17.30 g	7.65 g	10.20 g	14.25 g
Alanine	11.41 g	15.09 g	19.13 g	7.08 g	9.46 g	13.17 g
Argenine	6.34 g	8.38 g	10.63 g	3.93 g	5.26 g	7.31 g
Glycine	5.68 g	7.51 g	9.52 g	3.52 g	4.71 g	6.55 g
Histadine	2.64 g	3.50 g	4.44 g	1.64 g	2.19 g	3.05 g
Isoleucine	3.31 g	4.37 g	5.54 g	2.05 g	2.74 g	3.82 g
Leucine	4.02 g	5.32 g	6.75 g	2.50 g	3.34 g	4.64 g
Lysine ***(as lysine hydrochloride)***	3.20 g *(3.99 g)*	4.23 g *(5.29 g)*	5.36 g *(6.70 g)*	1.98 g *(2.48 g)*	2.65 g *(3.31 g)*	3.69 g *(4.61 g)*
Methionine	2.20 g	2.92 g	3.70 g	1.37 g	1.83 g	2.54 g
Phenylalanine	3.09 g	4.08 g	5.17 g	1.92 g	2.56 g	3.56 g
Proline	3.75 g	4.96 g	6.28 g	2.33 g	3.11 g	4.32 g
Serine	2.76 g	3.65 g	4.62 g	1.71 g	2.29 g	3.18 g
Threonine	2.31 g	3.06 g	3.88 g	1.44 g	1.92 g	2.67 g
Tryptophan	0.99 g	1.31 g	1.66 g	0.62 g	0.82 g	1.14 g
Tyrosine	0.22 g	0.29 g	0.37 g	0.14 g	0.18 g	0.25 g
Valine	3.20 g	4.23 g	5.36 g	1.98 g	2.65 g	3.69 g
Sodium acetate trihydrate	3.10 g	4.10 g	5.19 g	1.92 g	2.57 g	3.57 g
Potassium chloride	2.47 g	3.27 g	4.14 g	1.53 g	2.05 g	2.85 g
Calcium chloride dihydrate	0.41 g	0.54 g	0.68 g	0.25 g	0.34 g	0.47 g
Magnesium sulfate heptahydrate	1.36 g	1.80 g	2.28 g	0.84 g	1.13 g	1.57 g
Sodium glycerophosphate, hydrated	3.26 g	4.32 g	5.47 g	2.03 g	2.71 g	3.77 g
Zinc sulfate heptahydrate	0.013 g	0.017 g	0.021 g	0.008 g	0.011 g	0.015 g

Indications: Finomel / Finomel Peri is indicated for parenteral nutrition in adult patients when oral or enteral nutrition is impossible, insufficient or contra-indicated.

Dosage and route: *See SPC for details*: Single use only. Finomel should only be administered through a central line. Finomel Peri should be administered through a central or peripheral line – if a peripheral vein is used, the osmolarity should be considered and the site evaluated daily for signs of thrombophlebitis. The dosage should be individualised depending on energy expenditure, the patient's clinical status, body weight and ability to metabolise constituents of Finomel / Finomel Peri, as well as additional energy or proteins given orally/enterally. The bag size should be chosen accordingly. The maximum daily dose varies. The recommended infusion period is 14-24 hours. Safety/efficacy in children and adolescent less than 18 years of age has not been established.

Side effects: The frequency of these events cannot be estimated from available data. Hypersensitivity, refeeding syndrome, hyperglycaemia, dizziness, headache, thrombophlebitis, pulmonary embolism, respiratory distress, dyspnea, nausea, vomiting, pyrexia, extravasation, hepatic enzyme increased, fat overload syndrome, parenteral nutrition associated liver disease.

Precautions: There are no data from the use of Finomel / Finomel Peri in pregnant women or breast-feeding and should only be given after careful consideration. Stop the infusion immediately if any signs or symptoms of an allergic reaction develop. Finomel / Finomel Peri contains soya-bean oil, fish oil and egg phosphatides which may rarely cause allergic reactions. Cross allergic reactions have been observed between soybean and peanut. Finomel/Finomel Peri glucose is derived from corn, which may cause hypersensitivity reactions in patients with a corn/corn product allergy. Pulmonary precipitates causing vascular emboli and pulmonary distress have been reported in patients receiving parenteral nutrition, in some cases with fatal outcome. Inspect the solution, infusion set and catheter should be periodically checked for precipitates. If signs of pulmonary distress occur, the infusion should be stopped and medical evaluation initiated. Infection and sepsis is associated with intravenous administrations, use strict aseptic precautions. Fat overload syndrome has been reported with similar products. The syndrome is usually reversible when the infusion of the lipid emulsion is stopped. Patients with impaired lipid metabolism: use with caution; monitor triglycerides, the concentration should not exceed 4.6 mmol/L during infusion. Monitor serum glucose, electrolytes, fluid balance, acid-base balance, osmolarity, and liver enzymes. Refeeding severely undernourished patients may result in refeeding syndrome; careful monitoring and slowly increasing nutrient intake can prevent this complication. In malnourished patients, initiation of parenteral nutrition can cause fluid shifts resulting in pulmonary oedema and congestive heart failure with electrolyte and water soluble vitamin disturbances; careful/slow initiation of parenteral nutrition is recommended; closely monitor and appropriately adjust fluids, electrolytes, minerals and vitamins. Caution in patients with hepatic impairment, monitor liver function parameters closely. If hyperglycaemia occurs treat according to the clinical situation. Caution in patients with renal impairment, correct any fluid and/or electrolyte disturbances prior to starting the infusion and monitor carefully to avoid hyperphosphataemia, hypermagnesemia and/or hyperkalaemia. Monitor fluid and electrolyte balance, acid-base balance, serum osmolarity, triglycerides, blood glucose, liver and kidney function, blood count throughout treatment. Caution in patients with lactic acidosis, insufficient cellular oxygen supply and/or increased serum osmolarity. In long term use consider the dosing of trace elements, particularly copper and zinc. Caution in patients with pulmonary oedema or heart failure: monitor fluid status closely. The amino acid content may cause undesirable effects when the recommended infusion rate is exceeded. With an impaired renal function, increased levels of nitrogen containing metabolites may occur. Caution in patients with a tendency for electrolyte retention, stop the infusion if any abnormal signs occur. Administer using a volumetric pump where possible, to avoid risk associated with too rapid infusion rates.

Contraindications: Hypersensitivity to fish, egg, soya or peanut proteins, corn or corn products or any of the active substances or excipients. Severe hyperlipidaemia, hepatic impairment or blood coagulation disorders. Congenital abnormalities of amino acid metabolism, severe renal impairment without access to hemofiltration or dialysis, uncontrolled hyperglycaemia, pathologically elevated electrolyte levels of any of the included electrolytes, general contra-indications to infusion therapy: acute pulmonary oedema, hyperhydration and decompensated cardiac insufficiency. Unstable clinical conditions (e.g. severe post-traumatic conditions, uncompensated diabetes mellitus, acute myocardial infarction, stroke, embolism, metabolic acidosis, severe sepsis, hypotonic dehydration and hyperosmolar coma)

Interactions: No interaction studies have been performed with Finomel / Finomel Peri. Additions should be made aseptically. Do not administer simultaneously with blood through the same tubing. Ceftrioxone must not be administered simultaneously through the same line due to risk of precipitation. Soya-bean oil has a natural low content of Vitamin K_1 but is not expected to significantly influence the coagulation process in patient treated with coumarin derivatives. The lipid content may interfere with results of certain laboratory tests if the blood sample is taken before the lipids are eliminated (generally 5 to 6 hours without receiving lipids). See SPC for list of acceptable additives.

Overdose: Nausea, vomiting, chills, hyperglycaemia, electrolyte disturbances and signs of hypervolaemia or acidosis may occur. In such situations stop the infusion immediately. If hyperglycaemia occurs, treat according to the clinical situation. If symptoms persist after cessation of the infusion, haemodialysis, haemofiltration or haemodiafiltration may be considered.

Legal Category: POM

Marketing Authorisation Holder	Product Name; Marketing Authorisation number	Product Code	Bag Size	List Price (s) *
Baxter Healthcare Limited, Caxton Way, Thetford, Norfolk IP24 3SE.	FINOMEL, emulsion for infusion - PL00116/0661	1101319	1,085 ml	£50.49
		1101320	1,435 ml	£65.48
		1101321	1,820 ml	£69.06
	FINOMEL PERI, emulsion for infusion - PL00116/0660	1101322	1,085 ml	£39.09
		1101323	1,450 ml	£50.69
		1101324	2,020 ml	£58.77

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Adverse Events and any suspected defective medicines should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard.
Adverse Events relating to Baxter products can also be reported direct to Baxter Pharmacovigilance on +44 (0)1635 206360, or by email to vigilanceuk@baxter.com
Any drug product quality complaints (including suspected defective medicines) relating to Baxter products can be reported directly to the Baxter Country Quality Assurance Team on +44 (0)1604 704603, or by email to UK_SHS_QA_Complaints@baxter.com. Alternatively please report directly to your Baxter Representative, who will take the details and forward to the Baxter Country Quality Assurance Team.

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For the use by HCPs in the UK only.

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