

TRIOMEL RANGE PRESCRIBING INFORMATION - UK

Name and composition: TRIOMEL Peripheral 4g/l nitrogen 700kcal/l with electrolytes, TRIOMEL 5g/l nitrogen 990kcal/l with electrolytes, TRIOMEL 7g/l nitrogen 1140kcal/l with electrolytes, Triomel 7g/l nitrogen 1140 kcal/l, TRIOMEL 9g/l nitrogen 1070kcal/l with electrolytes TRIOMEL 9g/l nitrogen 1070kcal/l, TRIOMEL 12 g/l nitrogen 950 kcal/l with electrolytes and TRIOMEL 12 g/l nitrogen 950 kcal/l emulsions for infusion. Three-chamber bags, where 1000ml of reconstituted emulsion contains:

Active Ingredients	TRIOMEL Peripheral N4-700 with electrolytes	TRIOMEL N5-990 with electrolytes *	TRIOMEL N7-1140 with electrolytes	TRIOMEL N7-1140	TRIOMEL N9-1070 with electrolytes	TRIOMEL N9-1070	TRIOMEL N12-950 with electrolytes	TRIOMEL N12-950
Refined olive oil (~80%) + refined soya oil (~20%)	30.00g	40.00g	40.00g	40.00g	40.00g	40.00g	35.00g	35.00g
Alanine	3.66g	4.76g	6.41g	6.41g	8.24g	8.24g	10.99g	10.99g
Arginine	2.48g	3.23g	4.34g	4.34g	5.58g	5.58g	7.44g	7.44g
Aspartic acid	0.73g	0.95g	1.28g	1.28g	1.65g	1.65g	2.20g	2.20g
Glutamic acid	1.26g	1.65g	2.21g	2.21g	2.84g	2.84g	3.79g	3.79g
Glycine	1.76g	2.28g	3.07g	3.07g	3.95g	3.95g	5.26g	5.26g
Histidine	1.51g	1.97g	2.64g	2.64g	3.40g	3.40g	4.53g	4.53g
Isoleucine	1.26g	1.65g	2.21g	2.21g	2.84g	2.84g	3.79g	3.79g
Leucine	1.76g	2.28g	3.07g	3.07g	3.95g	3.95g	5.26g	5.26g
Lysine (equivalent to Lysine acetate)	1.99g (2.81g)	2.59g (3.65g)	3.48g (4.88g)	3.48g (4.88g)	4.48g (6.32g)	4.48g (6.32g)	5.97g (8.43g)	5.97g (8.43g)
Methionine	1.26g	1.65g	2.21g	2.21g	2.84g	2.84g	3.79g	3.79g
Phenylalanine	1.76g	2.28g	3.07g	3.07g	3.95g	3.95g	5.26g	5.26g
Proline	1.51g	1.97g	2.64g	2.64g	3.40g	3.40g	4.53g	4.53g
Serine	1.00g	1.30g	1.75g	1.75g	2.25g	2.25g	3.00g	3.00g
Threonine	1.26g	1.65g	2.21g	2.21g	2.84g	2.84g	3.79g	3.79g
Tryptophan	0.42g	0.55g	0.74g	0.74g	0.95g	0.95g	1.26g	1.26g
Tyrosine	0.06g	0.09g	0.11g	0.11g	0.15g	0.15g	0.20g	0.20g
Valine	1.62g	2.11g	2.83g	2.83g	3.64g	3.64g	4.86g	4.86g
Sodium acetate, 3H ₂ O	1.16g	1.49g	1.50g	-	1.50g	-	1.50 g	-
Sodium glycerophosphate, 5H ₂ O	1.91g	3.67g	3.67g	-	3.67g	-	3.67 g	-
Potassium chloride	1.19g	2.23g	2.24g	-	2.24g	-	2.24 g	-
Magnesium chloride, 6H ₂ O	0.45g	0.81g	0.81g	-	0.81g	-	0.81 g	-
Calcium chloride, 2H ₂ O	0.30g	0.51g	0.52g	-	0.52g	-	0.52 g	-
Glucose Anhydrous (equivalent to glucose monohydrate)	75.00g (82.50g)	115g (126.5g)	140.00g (154.00g)	140.00g (154.00g)	110.00g (121.00g)	110.00g (121.00g)	73.33g (80.67g)	73.33g (80.67g)

*composition of TRIOMEL N5-990 is calculated from the 1,500mL formulation in its Summary of Product Characteristics

Indications: Parenteral nutrition for adults and children greater than 2 years of age when oral or enteral nutrition is impossible, insufficient or contraindicated. **Dosage and Route:** Dosage will depend on energy expenditure, clinical condition, body weight and ability to metabolise constituents. Consider energy/proteins given orally/enterally. May continue for as long as is clinically required. Intravenous infusion. Triomel Peripheral 4g/l nitrogen 700kcal/l with electrolytes via a peripheral or central vein. All others, via a central vein only. Increase flow rate gradually, adjust to the formulation used, dosage, daily volume intake and duration of infusion. Maximum daily dose should not be exceeded. Due to static composition of multi-chamber bag it may not be possible to meet all nutrient needs. If patient requires nutrient amounts varying from composition of static bag volume (dose) adjustments must take into consideration resultant effect on dosing of all other nutrient components. **Side Effects:** See *Summary of Product Characteristics for detail*. Side effects may occur due to inappropriate use. Immediately stop infusion if sweating, fever, shivering, headaches, skin rashes or dyspnoea. Common Adverse Drug Reactions (ADRs): tachycardia, decreased appetite, hypertriglyceridaemia, abdominal pain, diarrhoea, nausea, hypertension. ADRs with frequency not known: thrombocytopaenia, cholestasis, hepatomegaly, jaundice, hypersensitivity, blood alkaline phosphatase, transaminases and blood bilirubin increase, elevated liver enzymes, injury, poisoning, procedural complications (registered in Triomel N12/N12E only), pulmonary vascular precipitates (pulmonary vascular embolism and respiratory distress) and azotemia. Extravasation which may result in infusion site pain, irritation, swelling/oedema, erythema/warmth, skin necrosis, blisters/vesicles, inflammation, induration, skin tightness. Very rare ADRs: fat overload syndrome. This syndrome is associated with a sudden deterioration in the patient's clinical condition and is characterized by findings such as fever, anemia, leukopenia, thrombocytopenia, coagulation disorders, hyperlipidemia, liver fatty infiltration (hepatomegaly), deteriorating liver function, and central nervous system manifestations (e.g. coma). The syndrome is usually reversible when infusion of the lipid emulsion is stopped. **Precautions:** Excessively fast administration may result in severe or fatal consequences. May cause hypersensitivity reactions to patients with allergy to corn/corn products. Ceftriaxone must not be mixed or administered with calcium-containing IV solutions even via different infusion lines or sites. They may be administered sequentially if infusion lines are replaced or thoroughly flushed between infusions. See SmPC for further guidance if use of ceftriaxone is considered necessary in patients requiring continuous nutrition and alternative antibacterial treatments are not possible. Excessive addition of calcium and phosphate increases risk of calcium phosphate precipitates. In addition to the solution, infusion sets and catheter should periodically be checked for precipitates. Stop infusion and medically evaluate if signs of respiratory distress occur. Correct fluid, electrolyte and metabolic disorders first. Monitor fluid and electrolyte balance, serum osmolarity, acid/base balance, blood glucose, liver and kidney function tests, coagulation and blood count. Patients requiring parenteral nutrition are often predisposed to infectious complications. Heighten emphasis on aseptic techniques. Monitor vascular access device for infectious complications and extravasation. Caution in, and regularly monitor if, amino acid metabolism disorders, hepatic insufficiency, renal insufficiency, metabolic acidosis, diabetes mellitus, coagulation disorders, anaemia and hyperlipidaemia. Patients developing signs of hepatobiliary disorders should be assessed early by a clinician (registered in Triomel N12 and N12E only). Regularly monitor serum triglycerides – not to exceed 3mmol/l during infusion, monitor daily if abnormality suspected. In adults, serum must be clear less than 6 hours after stopping the infusion. Thrombophlebitis may develop if hypertonic solutions administered peripherally. If additions are made, check admin route is suitable for final osmolarity. Caution if increased patient osmolarity, adrenal insufficiency, heart failure or pulmonary dysfunction. In paediatrics - use a bag volume corresponding to daily dosage. Vitamin and trace element supplementation always required (paediatric formulations). Use a continuous, controlled infusion rate. Caution in patients with tendency towards electrolyte retention. Check compatibility and stability of additions. Do not connect bags in series due to risk of air embolism. **Contraindications:** Children less than 2 years old, hypersensitivity to egg, soybean, peanut proteins or corn/corn products or to any ingredient, congenital abnormalities of amino acid metabolism, severe hyperlipidaemia or severe lipid metabolism disorders, hypertriglyceridaemia, severe hyperglycaemia, pathologically-elevated plasma concentrations of electrolytes. **Interactions:** Not to be administered through the same giving sets as blood - possible risk of pseudoagglutination. Lipids may interfere with certain laboratory tests if the sample is taken before they

have cleared. Do not co-administer with ceftriaxone – risk of precipitation. Special care with diuretics, ACE inhibitors, angiotensin II receptor antagonists, tacrolimus, cyclosporine. Heparin given in clinical doses causes a transient release of lipoprotein lipase into the circulation (registered in Triomel N12 and N12E only). **Overdose:** Where incorrect administration, overdose and/or excessively fast rate, signs of hypervolaemia and acidosis, hyperglycaemia, glycosuria and a hyperosmolar syndrome may occur. Nausea, vomiting, chills, headache, hot flush, hyperhidrosis and electrolyte disturbances may develop. May result in ‘fat overload syndrome’. Stop the infusion. In serious cases haemodialysis, haemofiltration or haemodiafiltration may be necessary. **Legal Category:** POM **Marketing Authorisation Holder:** Baxter Healthcare Limited, Caxton Way, Thetford, Norfolk IP24 3SE

Product Name	Marketing Authorisation	Code	Basic NHS Price
TRIOMEL Peripheral N4-700 with electrolytes 1.5 litre	0116/0641	FDB3WF1F	£50.69
TRIOMEL Peripheral N4-700 with electrolytes 1 litre	0116/0641	FDB3WF1E	£33.23
TRIOMEL Peripheral N4-700 with electrolytes 2 litre	0116/0641	FDB3WF1G	£58.77
TRIOMEL Peripheral N4-700 with electrolytes 2.5 litre	0116/0641	FDB3WF1H	£63.91
TRIOMEL N5-990 with electrolytes 2 litre	0116/0642	FDB3WK1G	£62.20
TRIOMEL N5-990 with electrolytes 2.5 litre	0116/0642	FDB3WK1H	£67.64
TRIOMEL N7-1140 with electrolytes 1.5 litre	0116/0643	FDB3WG1F	£59.56
TRIOMEL N7-1140 with electrolytes 2 litre	0116/0643	FDB3WG1G	£69.06
TRIOMEL N7-1140 1.5 litres	0116/0644	FDB3XG1F	£59.56
TRIOMEL N9-1070 with electrolytes 1 litre	0116/0645	FDB3WP1E	£50.49
TRIOMEL N9-1070 with electrolytes 2 litre	0116/0645	FDB3WP1G	£75.92
TRIOMEL N9-1070 1.5 litre	0116/0646	FDB3XP1F	£65.48
TRIOMEL N9-1070 2 litre	0116/0646	FDB3XP1G	£75.92
TRIOMEL N12 with electrolytes 650 ml	0116/0662	FDB3WH1C	£40.95
TRIOMEL N12 with electrolytes 1 litre	0116/0662	FDB3WH1E	£57.33
TRIOMEL N12 with electrolytes 1.5 litre	0116/0662	FDB3WH1F	£74.36
TRIOMEL N12 with electrolytes 2 litre	0116/0662	FDB3WH1G	£86.22
TRIOMEL N12 650 ml	0116/0663	FDB3XH1C	£40.95
TRIOMEL N12 1 litre	0116/0663	FDB3XH1E	£57.33
TRIOMEL N12 1.5 litre	0116/0663	FDB3XH1F	£74.36
TRIOMEL N12 2 litre	0116/0663	FDB3XH1G	£86.22

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