TRIOMEL RANGE PRESCRIBING INFORMATION – Republic of Ireland

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 1140kcal/l, Triomel 9g/l nitrogen 1070kcal/l with electrolytes, Triomel 9g/l nitrogen 1070kcal/l emulsions for infusion, Triomel 12 g/l nitrogen 950 kcal/l with electrolytes, emulsion for infusion and Triomel 12 g/l nitrogen 950 kcal/l, emulsion 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-bean oil (~20%)	30.00 g	40.00g	40.00 g	40.00 g	40.00 g	40.00 g	35.00g	35.00g
Alanine	3.66 g	4.76g	6.41 g	6.41 g	8.24 g	8.24 g	10.99g	10.99g
Arginine	2.48 g	3.23g	4.34 g	4.34 g	5.58 g	5.58 g	7.44g	7.44g
Aspartic acid	0.73 g	0.95g	1.28 g	1.28 g	1.65 g	1.65 g	2.20g	2.20g
Glutamic acid	1.26 g	1.65g	2.21 g	2.21 g	2.84 g	2.84 g	3.79g	3.79g
Glycine	1.76 g	2.28g	3.07 g	3.07 g	3.95 g	3.95 g	5.26g	5.26g
Histidine	1.51 g	1.97g	2.64 g	2.64 g	3.40 g	3.40 g	4.53g	4.53g
Isoleucine	1.26 g	1.65g	2.21 g	2.21 g	2.84 g	2.84 g	3.79g	3.79g
Leucine	1.76 g	2.28g	3.07 g	3.07 g	3.95 g	3.95 g	5.26g	5.26g
Lysine (equivalent to Lysine acetate)	1.99 g (2.81 g)	2.59g (3.65g)	3.48 g (4.88g)	3.48 g (4.88g)	4.48 g (6.32g)	4.48 g (6.32g)	5.97g (8.43g)	5.97g (8.43g)
Methionine	1.26 g	1.65g	2.21 g	2.21 g	2.84 g	2.84 g	3.79g	3.79g
Phenylalanine	1.76 g	2.28g	3.07 g	3.07 g	3.95 g	3.95 g	5.26g	5.26g
Proline	1.51 g	1.97g	2.64 g	2.64 g	3.40 g	3.40 g	4.53g	4.53g
Serine	1.00 g	1.30g	1.75 g	1.75 g	2.25 g	2.25 g	3.00g	3.00g
Threonine	1.26 g	1.65g	2.21 g	2.21 g	2.84 g	2.84 g	3.79g	3.79g
Tryptophan	0.42 g	0.55g	0.74 g	0.74 g	0.95 g	0.95 g	1.26g	1.26g
Tyrosine	0.06 g	0.09g	0.11 g	0.11 g	0.15 g	0.15 g	0.20g	0.20g
Valine	1.62 g	2.11g	2.83 g	2.83 g	3.64 g	3.64 g	4.86g	4.86g
Sodium acetate, $3H_2O$	1.16 g	1.49g	1.50 g	-	1.50 g	-	1.5 g	-
Sodium glycerophosphate, $5H_2O$	1.91 g	3.67g	3.67 g	-	3.67 g	-	3.67 g	-
Potassium chloride	1.19 g	2.23g	2.24 g	-	2.24 g	-	2.24 g	-
Magnesium chloride, $6H_2O$	0.45 g	0.81g	0.81 g	-	0.81 g	-	0.81 g	-
Calcium chloride, $2H_2O$	0.30 g	0.51g	0.52 g	-	0.52 g	-	0.52 g	-
Glucose (equiv' to glucose monohydrate)	75.00 g (82.50g)	115g (126.5g)	140.00 g (154.00g)	140.00 g (154.00g)	110.00 g (121.00g)	110.00 g (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, hypertriglyceridemia, abdominal pain, diarrhoea, nausea, hypertension. ADRs with frequency not known: vomiting, thrombocytopenia, cholestasis, hepatomegaly, jaundice, hypersensitivity reactions (hyperhidrosis, pyrexia, chills, headache, skinrash, pruritus, hot flush, dyspnoea), blood alkaline phosphatase, transaminases and blood bilirubin increased, elevated liver enzymes, injury, poisoning, procedural complications, pulmonary vascular precipitates (pulmonary vascular embolism and respiratory distress; sometimes fatal) 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 characterised 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 in patients with corn allergy. 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. Stop infusion immediately if any signs of an allergic reaction develop. 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. Regularly monitor serum triglycerides – not to exceed 3 mmol/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. 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. Caution on dose selection for an elderly patient. **Contraindications**: Children less than 2 years old, hypersensitivity to egg, soya-bean, peanut proteins, corn/corn products or to any ingredient, congenital abnormalities of amino acid metabolism, severe hyperlipidaemia or severe lipid metabolism disorders, hypertriglyceridemia, severe hyperglycemia, 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 potassium-sparing diuretics, ACE inhibitors, angiotensin II receptor antagonists, tacrolimus, cyclosporine. Heparin given in clinical doses causes a transient release of lipoprotein lipase into the circulation. **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 haemo-diafiltration may be necessary. **Legal category:** POM **Marketing Authorisation Holder:** Baxter Holding B.V., Kobaltweg 49, 3542CE Utrecht, Netherlands

Product Name	Marketing Authorization
Triomel N4-700 with electrolytes 1L,1.5L, 2L & 2.5L	PA 2299/029/001
Triomel N5-990 with electrolytes 2L & 2.5L	PA 2299/029/002
Triomel N7-1140 with electrolytes 1.5L and 2L	PA 2299/029/003
Triomel N7-1140 1.5 litre	PA 2299/029/004
Triomel N9-1070 with electrolytes 1L & 2L	PA 2299/029/005
Triomel N9-1070 1.5L & 2L	PA 2299/029/006
Triomel 12 g/l nitrogen 950 kcal/l with electrolytes, 650mL, 1L, 1.5L, 2L	PA 2299/043/007
Triomel 12 g/l nitrogen 950 kcal/l 650mL, 1L, 1.5L, 2L	PA 2299/043/008

Date of preparation: October 2020