Baxter

Numeta (glucose solution, lipid emulsion, paediatric amino acids & electrolytes)

Triomel (glucose, calcium, lipid emulsion, amino acids & electrolytes)

BAXTER READY-TO-USE PARENTERAL NUTRITION MULTI-CHAMBER BAGS (MCBs)

Solutions to improve patient outcomes and support your environmental sustainability goals.

Commercially prepared ready-to-use MCBs may offer many benefits compared to custom compounded parenteral nutrition (PN) while supporting environmentally responsible goals:

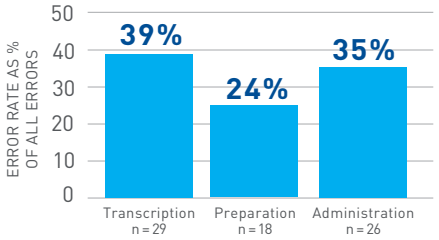
MCBs SAVE PREPARATION TIME[1]

38 fewer minutes per bag

~65% less preparation time vs. Compounded PN

USING MCBs MAY LOWER THE INCIDENCE OF COMPOUNDING ERRORS[5]

Medication errors associated with transcription, preparation and administration of compounded PN[4]



A total of 4730 PN prescriptions were written during the study. Of these, 74 (1.6%) of the total prescriptions were associated with a medication error.

Adapted from Sacks G, et al. Pharmacotherapy 2009; 8:966-74

MCBs MAY LOWER THE RISK OF INFECTION[3,6,7]

Each compounded PN solution can contain

= up to **10** different solutions containing up to **50** components

Adapted from Puntis J, et al. Sigma Vitae 2010;5:8-12

19% 19% lower probability for bloodstream infection vs. Compounded PN (24.9% vs. 29.6%, odd ratio = 1.29)[2]

LOWER RATES OF INFECTION MAY REDUCE PATIENT LENGTH OF STAY

PN patients on MCBs had a reduced ICU stay by **2.2 days** vs. patients on Compounded PN (9.1 vs 11.3 days, p<.001)[2]

PN patients on MCBs had a reduced hospital length of stay by **3.2 days** vs. patients on Compounded PN (19.4 vs. 22.6, p<.001)[2]

Reducing patient Length of Stay (LOS) may help you reach your sustainability goals.

MCBs MAY CONSERVE NATURAL RESOURCES SUCH AS WATER AND ENERGY, AND REDUCE WASTE.[2,8]

A length of stay reduction may reduce hospital environmental impacts.

Day to day patient activities have an impact on your Hospitals' environmental footprint, for example:

- Fewer flushes - 128 toilet flushes = 768 litres of water[9]
- Less energy consumption - 15 days use of 40" HDTV = 85 kWh energy consumption[10]
- Less rubbish produced - 2 x 49-litre rubbish bins = 11 kg waste[11]

While focusing on patient safety, improving sustainability and performance with Baxter MCBs may:

- Reduce patient length of stay
- Reduce medication error, infection risk, and save preparation time
- Conserve natural resources

Baxter Parenteral Nutrition Multi-Chamber Bags – A positive impact for patient outcome, and environmental and sustainability goals.

REFERENCES:

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2. Pontes-Arruda A, Zaloga G, Wischmeyer P, Turpin R, Liu FX, Mercaldi C. Is there a difference in bloodstream infections in critically ill patients associated with ready-to-use versus compounded parenteral nutrition? *Clin Nutr.* 2012 Oct;31(5):728-34.
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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

TRIOMEL RANGE PRESCRIBING INFORMATION - UK

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Refined olive oil (~80%) + refined soya-bean 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
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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
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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
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Potassium chloride	1.19g	2.23g	2.24g	-	2.24g	-	2.24 g	-
Magnesium chloride, $6H_2O$	0.45g	0.81g	0.81g	-	0.81g	-	0.81 g	-
Calcium chloride, $2H_2O$	0.30g	0.51g	0.52g	-	0.52g	-	0.52 g	-
Glucose (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)

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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. 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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	FDB-3WK1H	£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

Date of preparation: August 2020

NUMETA RANGE PRESCRIBING INFORMATION – Ireland

Name and composition: Numeta G13%E Preterm, Numeta G16%E, Numeta G19%E.
Active Substance: Reconstituted triple chamber bag contains:

Active Ingredients	Numeta G13%E Preterm	Numeta G16%E	Numeta G19%E
Amino Acid Chamber			
Alanine	0.75g	1.03g	1.83g
Arginine	0.78g	1.08g	1.92g
Aspartic acid	0.56g	0.77g	1.37g
Cysteine	0.18g	0.24g	0.43g
Glutamic acid	0.93g	1.29g	2.29g
Glycine	0.37g	0.51g	0.91g
Histidine	0.35g	0.49g	0.87g
Isoleucine	0.62g	0.86g	1.53g
Leucine	0.93g	1.29g	2.29g
Lysine monohydrate (equivalent to Lysine)	1.15g (1.03g)	1.59g (1.42g)	2.82g (2.51g)
Methionine	0.22g	0.31g	0.55g
Ornithine hydrochloride (equiva-lent to ornithine)	0.30g (0.23g)	0.41g (0.32g)	0.73g (0.57g)
Phenylalanine	0.39g	0.54g	0.96g
Proline	0.28g	0.39g	0.69g
Serine	0.37g	0.51g	0.91g
Taurine	0.06g	0.08g	0.14g
Threonine	0.35g	0.48g	0.85g
Tryptophan	0.19g	0.26g	0.46g
Tyrosine	0.07g	0.10g	0.18g
Valine	0.71g	0.98g	1.74g
Sodium chloride	0g	0.30g	1.79g
Potassium acetate	0.61g	1.12g	3.14g
Calcium chloride dihydrate	0.55g	0.46g	0.56g
Magnesium acetate tetrahydrate	0.10g	0.33g	0.55g
Sodium glycerophosphate hydrated	0.98g	0.98g	2.21g
Glucose Chamber			
Glucose Anhydrous (equivalent to glucose monohydrate)	44.00g (40.00g)	85.25g (77.50g)	210.65g (191.50g)
Lipid Chamber			
Refined olive oil (~80%) + refined soya oil (~20%)	7.5g	15.5g	28.1g

If lipids not required, bag design allows activation of peel seals between amino acids/electrolytes and glucose chambers only. **Indications**: Parenteral Nutrition when oral or enteral nutrition is not possible, insufficient or contraindicated: Numeta: G13%E Preterm – preterm newborn infants, G16%E - term newborn infants and children up to 2 years, G19%E – Children older than 2 years and adolescents 16-18 years. **Dosage and Route**: Dependant on clinical condition and metabolism. Continue for as long as clinically required. Administer via central vein or dilute with sufficient water for injection for peripheral infusion. Adjust administration rate gradually, according to formulation used, dosage, daily volume intake and duration of infusion. **Side effects**: see Summary of Product Characteristics (SPC) for detail. Common: Hypophospha-taemia, Hyperglycaemia, Hypercalcaemia, Hypertriglyceridaemia, and Hyponatrae-mia. Uncommon: Pulmonary vascular precipitates, cholestasis, Hyperlipidaemia and fat overload syndrome (reversible when lipid infusion stopped). Not known: Skin necrosis, Soft tissue injury and Extravasation. **Precautions**: Stop infusion immediately if signs or symptoms of allergic reaction develop (fever, sweating, shivering, headache, skin rashes or dyspnoea). Ceftriaxone must not be mixed or administered with intravenous calcium-containing solutions, including Numeta. In patients older than 28 days cef-triaxone and calcium-containing solutions may be administered sequentially. See SPC for further guidance. Pulmonary vascular precipitates causing pulmonary vas-cular embolism and respiratory distress have been reported in patients receiving parenteral nutrition. Excessive addition of calcium and phosphate increases risk of formation of calcium phosphate precipitates. The solution, infusion set and catheter should periodically be checked for precipitates. If there are signs of respiratory dis-tress stop infusion and initiate medical evaluation. Refeeding syndrome (character-ised by shift in intracellular electrolytes), thiamine deficiency and fluid retention may also develop. Correct fluid, electrolyte and metabolic disorders before use. Lipids, vitamins, electrolytes and trace elements should be administered as required. Fol-low aseptic procedures for catheter placement, maintenance and nutritional formu-la preparation since patients requiring parenteral nutrition are often predisposed to infectious complications. Check compatibility of additions – risk of occlusion from precipitate formation. With additions the final osmolarity must be measured before administration via peripheral vein to avoid vein irritation. When used in neonates and children below 2 years, Numeta should be protected from light until administration is completed. Routine-ly monitor water and electrolyte balance (particularly magnesium, as signs of hy-permagnesaemia may not be detected), serum osmolarity, triglycerides, acid/base balance, blood glucose, hepatic and renal function, blood count and coagulation parameters throughout treatment. Numeta G16%E provides 0.3mmol/kg/day magnesium at maximum dose. If serum magnesium levels are elevated, stop or reduce infusion rate as clinically appropriate. Adjust administration to meet clinical needs in unstable conditions (e.g. following sever post-traumatic conditions). Caution in pulmonary oedema, heart failure, hepatic insufficiency, renal insufficiency and severe blood coagulation disorders. Monitor for endocrine and metabolic complications. Fat overload syndrome may develop. **Contraindications**: As activated 2 chamber bag - hypersensitivity to egg, soy or peanut proteins, or any active substances, excipients, or components of the container; congenital abnormality of amino acid metabolism; Pathologically elevated plasma concentrations of sodium, potassium, magnesium, calcium and/or phosphorus; severe hyperglycaemia. As above for the activated 3 chamber bag (with lipids) also, severe hyperlipidaemia or severe disorders of lip-id metabolism characterized by hypertriglyceridemia. G13%E Preterm and G16%E: concomitant treatment with ceftriaxone in preterm newborn and in term newborn infants (≤28 days of age), even if separate infusion lines are used (risk of fatal cef-triaxone calcium salt precipitation in the neonate´s bloodstream). **Interactions**: Do not administer simultaneously with blood through same infusion tubing due to risk of pseudoagglutination. Do not mix or co-administer with ceftriaxone, take special care with coumarins & their derivatives, potassium sparing diuretics, ACE Inhibitors, angiotensin II receptor antagonists, tacrolimus and cyclosporine. Lipids may inter-fere with certain laboratory tests if the sample is taken before they have cleared. **Overdose**: In the event of incorrect administration, overdose and/or infusion rate higher than recommended, signs of hypervolaemia and acidosis, hyperglycaemia, glycosuria and a hyperosmolar syndrome may occur. Nausea, vomiting, shivering and electrolyte disturbances may develop. Reduced /limited ability to metabolize lip-ids may result in fat overload syndrome. Stop infusion immediately. Emergency pro-cedures should be general supportive measures, particular attention to respiratory and cardiovascular systems. **Legal Category**: POM **Marketing Authorisation Holder**: Baxter Holding B.V. Kobaltweg 49, 3542CE Utrecht, Netherlands

Product Name	Marketing Authorisation
Numeta G13%E Preterm	PA 2299/030/003
Numeta G16%E	PA 2299/030/001
Numeta G19%E	PA 2299/030/002

Date of preparation: December 2020

NUMETA RANGE PRESCRIBING INFORMATION – UK

Name and composition: Numeta G13%E Preterm, Numeta G16%E, Numeta G19%E. Active Substance: Reconstituted triple chamber bag contains:

Active Ingredients	Numeta G13%E Preterm	Numeta G16%E	Numeta G19%E
Amino Acid Chamber			
Alanine	0.75g	1.03g	1.83g
Arginine	0.78g	1.08g	1.92g
Aspartic acid	0.56g	0.77g	1.37g
Cysteine	0.18g	0.24g	0.43g
Glutamic acid	0.93g	1.29g	2.29g
Glycine	0.37g	0.51g	0.91g
Histidine	0.35g	0.49g	0.87g
Isoleucine	0.62g	0.86g	1.53g
Leucine	0.93g	1.29g	2.29g
Lysine monohydrate (equivalent to Lysine)	1.15g (1.03g)	1.59g (1.42g)	2.82g (2.51g)
Methionine	0.22g	0.31g	0.55g
Ornithine hydrochloride (equivalent to ornithine)	0.30g (0.23g)	0.41g (0.32g)	0.73g (0.57g)
Phenylalanine	0.39g	0.54g	0.96g
Proline	0.28g	0.39g	0.69g
Serine	0.37g	0.51g	0.91g
Taurine	0.06g	0.08g	0.14g
Threonine	0.35g	0.48g	0.85g
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Uncommon: Pulmonary vascular precipitates, cholestasis, Hyperlipidaemia and fat overload syndrome (reversible when lipid infusion stopped). Not known: Skin necrosis, Soft tissue injury and Extravasation. Precautions: Stop infusion immediately if signs or symptoms of allergic reaction develop (fever, sweating, shivering, headache, skin rashes or dyspnoea). Caution in patients with known allergy to corn or corn products. Ceftriaxone must not be mixed or administered with intravenous calcium-containing solutions, including Numeta. In patients older than 28 days ceftriaxone and calcium-containing solutions may be administered sequentially. See SPC for further guidance. Pulmonary vascular precipitates causing pulmonary vascular embolism and respiratory distress have been reported in patients receiving parenteral nutrition. Excessive addition of calcium and phosphate increases risk of formation of calcium phosphate precipitates. The solution, infusion set and catheter should periodically be checked for precipitates. If there are signs of respiratory distress stop infusion and initiate medical evaluation. Refeeding syndrome (characterised by shift in intracellular electrolytes), thiamine deficiency and fluid retention may also develop. Correct fluid, electrolyte and metabolic disorders before use. Lipids, vitamins, electrolytes and trace elements should be administered as required. Follow aseptic procedures for catheter placement, maintenance and nutritional formula preparation since patients requiring parenteral nutrition are often predisposed to infectious complications. Check compatibility of additions – risk of occlusion from precipitate formation. With additions the final osmolarity must be measured before administration via peripheral vein to avoid vein irritation or tissue damage in case of extravasation of the solution. When use in neonates and children below 2 years, Numeta should be protected from light until administration is completed. Routinely monitor water and electrolyte balance (particularly magnesium, as signs of hypermagnesaemia may not be detected), serum osmolarity, triglycerides, acid/base balance, blood glucose, hepatic and renal function, blood count and coagulation parameters throughout treatment. Adjust administration to meet clinical needs in unstable conditions (e.g. following severe post-traumatic conditions). Caution in pulmonary oedema, heart failure, hepatic insufficiency, renal insufficiency and severe blood coagulation disorders. Monitor for endocrine and metabolic complications. Fat overload syndrome may develop. 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Product Name	Marketing Authorisation	Code	Price
Numeta G13%E Preterm	PL 00116/0659	FDB9601	£73.04
Numeta G16%E	PL 00116/0648	FDB9612	£84.35
Numeta G19%E	PL 00116/0649	FDB9623	£107.55

Date of preparation: October 2020

Adverse Events and any drug product quality complaints (including suspected defective medicines) should be reported. For the UK reporting forms and information can be found at www.mhra.gov.uk/yellowcard. For Ireland report to the Health Products Regulatory Authority (HPRA) using a Yellow Card obtained from the HPRA, via the online system (www.hpra.ie) or by telephone on +353 (0)1-6764971.

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 relating to Baxter products can be reported directly to the Baxter Country Quality Assurance Team: In the UK +44 (0)1604 704603, or by email to UK_SHS_QA_Complaints@baxter.com.
In Ireland on +353 (0)1 2065500 or by email to shs_complaints_dublin@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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UKI-00-230008 February 2023