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 (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
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: Hypophosphataemia, Hyperglycaemia, Hypercalcaemia, Hypertriglyceridaemia, and Hyponatraemia. Uncommon: Pulmonary vascular precipitates, cholestasis, Hyperlipidaemia and fat overload syndrome (reversible when lipid infusion stopped). **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 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. When used 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. 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 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. **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 lipid metabolism characterized by hypertriglyceridemia. G13%E 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 ceftriaxone 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 interfere 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 lipids may result in fat overload syndrome. Stop infusion immediately. Emergency procedures 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

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