User guide

TRIOMEL
OPTIMISED NUTRITIONAL BALANCE

1 Route of administration
2 Nitrogen and total kcal
3 Electrolyte content
4 Administration outlet
5 Key content information
6 Volume
7 Compartment identification
8 Injection site (for additions)

		Containing electrolytes				Without electrolytes	
		N4	N5	N7	N9	N7	N9
		TRIOMEL PERIPHERAL **4 g/l nitrogen** 700 kcal/l	TRIOMEL **5 g/l nitrogen** 990 kcal/l	TRIOMEL **7 g/l nitrogen** 1140 kcal/l	TRIOMEL **9 g/l nitrogen** 1070 kcal/l	TRIOMEL **7 g/l nitrogen** 1140 kcal/l	TRIOMEL **9 g/l nitrogen** 1070 kcal/l
Route of administration		Intravenous via **central or peripheral** vein	Intravenous via **central** vein **only**	Intravenous via **central** vein **only**	Intravenous via **central** vein **only**	Intravenous via **central** vein **only**	Intravenous via **central** vein **only**
Max hourly rate (ml/kg/h)	2–11 yrs	4.3	3.3	3.3	3.3	3.3	3.3
	12–18 yrs	4.3	3.3	2.7	2.1	2.7	2.1
	Adults	3.2	2.1	1.7	1.8	1.7	1.8
Recommended flow rate		Adults: flow rate must be increased gradually during the first hour and then adjusted to take into account the dose being administered, the daily volume intake and the duration of the infusion. Small children: start the infusion with a low daily dose and gradually increase it up to the maximum dosage.					
Recommended duration of infusion		12–24 hours					
Electrolytes and supplementation (mmol per 1000 ml)							
Sodium	Included level	21	35	35	35	0	0
	Max further addition*	129	115	115	115	150	150
	Max total level	150	150	150	150	150	150
Potassium	Included level	16	30	30	30	0	0
	Max further addition*	134	120	120	120	150	150
	Max total level	150	150	150	150	150	150
Magnesium	Included level	2.2	4	4	4	0	0
	Max further addition*	3.4	1.6	1.6	1.6	5.6	5.6
	Max total level	5.6	5.6	5.6	5.6	5.6	5.6
Calcium	Included level	2	3.5	3.5	3.5	0	0
	Max further addition*	3 (1.5†)	1.5 (0†)	1.5 (0†)	1.5 (0†)	5 (3.5†)	5 (3.5†)
	Max total level	5 (3.5†)	5 (3.5†)	5 (3.5†)	5 (3.5†)	5 (3.5†)	5 (3.5†)
Inorganic phosphate	Included level	0	0	0	0	0	0
	Max further addition*	8	3	3	3	8	8
	Max total level	8	3	3	3	8	8
Organic phosphate	Included level	8.5‡	15‡	15‡	15‡	3‡	3‡
	Max further addition*	15	10	10	10	22	22
	Max total level	23.5‡	25‡	25‡	25‡	25‡	25‡

*According to maximum total level tested in stability studies. †Value corresponding to the addition of inorganic phosphate. ‡Including phosphate provided by the lipid emulsion.
For detailed information please refer to the corresponding Summary of Product Characteristics.

1 CHECK the Oxydetect

OK

Check the colour of the oxygen indicator before opening the overpouch.

2 OPEN the overpouch

Peel the front of the overpouch open. Discard the overpouch and Oxydetect.

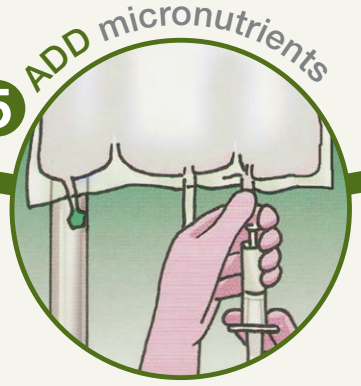
3 ROLL the bag

Place the bag flat and roll it onto itself starting from the hanger end. Roll until the nonpermenant seals are opened along approximately half of the bag.

4 MIX the contents

Mix by inverting the bag at least 3 times.

5 ADD micronutrients



Add micronutrients, in line with NICE[1] recommendations, according to the clinical needs of the patient and stability of the bag. Any additions may be made into the reconstituted mixture. Vitamins may be added into the glucose compartment before reconstitution. All additions should be made in the pharmacy[1,2] and mixed with the contents of the bag.

6 ADMINISTER TRIOMEL

Hang the bag and twist off the protector from the administration outlet. Firmly insert the spike of the infusion set into the administration port. The recommended duration of infusion is 12–24 hours.

BEFORE ADMINISTRATION: Check the route, rate and duration of administration

Bag preparation best practice

- Only proceed with preparation of the bag if:
  - The unopened bag is not damaged and the nonpermanent seals are intact (i.e. the contents of the 3 compartments have not mixed)
  - The amino acid solution and the glucose solution are clear, colourless or slightly yellow and practically free of visible particles
  - The lipid emulsion is homogeneous with a milky appearance
- Ensure the bag is at room temperature when breaking the nonpermanent seals
- Never pull on the seals
- It is recommended that the bag is used immediately after the nonpermanent seals have been opened; however, stability of the reconstituted mixture has been demonstrated for 7 days at 2–8°C followed by 48 hours at no higher than 25°C
- Always use aseptic technique

References: 1. NICE Clinical Guideline 32. Nutritional support for adults: oral nutrition support, enteral tube feeding and parenteral nutrition. 2006.
2. NHS National Patient Safety Agency. Patient Safety Alert 20. 2007.

Prescribing information can be found on the reverse.

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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 1140kcal/l, TRIOMEL 9g/l nitrogen 1070kcal/l with electrolytes, and TRIOMEL 9g/l nitrogen 1070kcal/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
Refined olive oil (~80%) + refined soya oil (~20%)	30.00g	40.00g	40.00g	40.00g	40.00g	40.00g
Alanine	3.66g	4.76g	6.41g	6.41g	8.24g	8.24g
Arginine	2.48g	3.23g	4.34g	4.34g	5.58g	5.58g
Aspartic acid	0.73g	0.95g	1.28g	1.28g	1.65g	1.65g
Glutamic acid	1.26g	1.65g	2.21g	2.21g	2.84g	2.84g
Glycine	1.76g	2.28g	3.07g	3.07g	3.95g	3.95g
Histidine	1.51g	1.97g	2.64g	2.64g	3.40g	3.40g
Isoleucine	1.26g	1.65g	2.21g	2.21g	2.84g	2.84g
Leucine	1.76g	2.28g	3.07g	3.07g	3.95g	3.95g
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)
Methionine	1.26g	1.65g	2.21g	2.21g	2.84g	2.84g
Phenylalanine	1.76g	2.28g	3.07g	3.07g	3.95g	3.95g
Proline	1.51g	1.97g	2.64g	2.64g	3.40g	3.40g
Serine	1.00g	1.30g	1.75g	1.75g	2.25g	2.25g
Threonine	1.26g	1.65g	2.21g	2.21g	2.84g	2.84g
Tryptophan	0.42g	0.55g	0.74g	0.74g	0.95g	0.95g
Tyrosine	0.06g	0.09g	0.11g	0.11g	0.15g	0.15g
Valine	1.62g	2.11g	2.83g	2.83g	3.64g	3.64g
Sodium acetate, $3H_2O$	1.16g	1.49g	1.50g	-	1.50g	-
Sodium glycerophosphate, $5H_2O$	1.91g	3.67g	3.67g	-	3.67g	-
Potassium chloride	1.19g	2.23g	2.24g	-	2.24g	-
Magnesium chloride, $6H_2O$	0.45g	0.81g	0.81g	-	0.81g	-
Calcium chloride, $2H_2O$	0.30g	0.51g	0.52g	-	0.52g	-
Glucose Anhydrous (equivalent to glucose monohydrate)	75.00g (82.50g)	115g (126.5g)	140.00g (154.00g)	140.00 g (154.00g)	110.00g (121.00g)	110.00g (121.00g)

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 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. **Side Effects:** *See Summary of Product Characteristics for detail.* Side effects may occur due to inappropriate use. Stop infusion if sweating, fever, shivering, headaches, skin rashes or dyspnoea.Frequency not known – thrombocytopaenia, hepatomegaly, jaundice, hypersensitivity, blood alkaline phosphatase, transaminases and blood bilirubin increase and azotemia. Very rare – fat overload syndrome. Common – tachycardia, anorexia, hypertriglyceridemia, abdominal pain, nausea, hypertension. **Precautions:** 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. 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. 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. 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 to any ingredient, congenital abnormalities of amino acid metabolism, severe hyperlipidaemia, 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, cyclophosporine. **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 and electrolyte disturbances may develop. Stop the infusion. In serious cases haemodialysis, haemofiltration or haemo-diafiltration 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 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 litre	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

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Any adverse events relating to Baxter products can also be reported direct to Baxter Pharmacovigilance on 01635 206360, or by email to vigilanceuk@baxter.com

Date of preparation: July 2014

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Product Name	Marketing Authorisation
TRIOMEL N4-700 with electrolytes 1.5L, 2L & 2.5L	PA 167/137/1
TRIOMEL N5-990 with electrolytes 2L & 2.5L	PA 167/137/2
TRIOMEL N7-1140 with electrolytes 1.5L and 2L	PA 167/137/3
TRIOMEL N7-1140 1.5 litre	PA 167/137/4
TRIOMEL N9-1070 with electrolytes 1L & 2L	PA 167/137/5
TRIOMEL N9-1070 1.5L & 2L	PA 167/137/6

Baxter Healthcare encourages healthcare professionals to continue to be vigilant and to report suspected adverse reactions to the Health Products Regulatory Authority (HPRA), Kevin O'Malley House, Earlsfort Centre, Earlsfort Terrace, IRL - Dublin 2 (online at www.hpra.ie, by email to info@hpra.ie, telephone 01-6764971 or using the yellow card system). Any 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

Date of preparation: July 2014

MALTA: Suspected adverse events should be reported to: ADR Reporting, The Medicines Authority, Post-Licensing Directorate 203 Level 3, Rue D'Argens, GŻR-1368 Gżira. Website: www.medicinesauthority.gov.mt email: postlicensing.medicinesauthority@gov.mt. Any 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

Malta Distributor:

For further information about TRIOMEL, please contact:

Drugsales Ltd.
Tel: +356 21 419 070/1/2 **email:** safety@drugsalesltd.com

Baxter Healthcare Ltd:
Medication Delivery, Wallingford Road, Compton,
Newbury, Berkshire RG20 7QW.
Tel: +44 (0) 1635 206060 **Fax:** +44 (0) 870 8507075
email: servicecs@baxter.com
www.baxterhealthcare.co.uk

Baxter Healthcare Ltd:
7 Deansgrange Business Park,
Blackrock, Co. Dublin.
Tel: +353 1 2065500 **Fax:** +353 1 2065555
www.baxterhealthcare.ie

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Clinical and technical information at the speed you need
– supporting the optimum use of Baxter products for patients.
Tel: +44 (0) 1635 206345 **Fax:** +44 (0) 1635 206071
email: surecall@baxter.com

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