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Baxter

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

TRIOMEL 7 g/l nitrogen 1140 kcal/l with electrolytes, emulsion for infusion

Read all of this leaflet carefully before you will be administered this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- If you get any side effect, talk to your doctor or nurse. This includes any side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What TRIOMEL 7 g/l nitrogen 1140 kcal/l with electrolytes, emulsion for infusion is and what it is used for
2. What you need to know before TRIOMEL 7 g/l nitrogen 1140 kcal/l with electrolytes, emulsion for infusion is administered
3. How TRIOMEL 7 g/l nitrogen 1140 kcal/l with electrolytes, emulsion for infusion will be used
4. Possible side effects
5. How TRIOMEL 7 g/l nitrogen 1140 kcal/l with electrolytes, emulsion for infusion is stored
6. Contents of the pack and other information

1. What TRIOMEL 7 g/l nitrogen 1140 kcal/l with electrolytes, emulsion for infusion is and what it is used for

TRIOMEL is an emulsion for infusion. It is presented in a bag with 3 chambers.

One chamber contains a glucose solution with calcium, the second one contains a lipid emulsion and the third one contains an amino acid solution with other electrolytes.

TRIOMEL is used to provide nutrition to adults and children greater than 2 years of age by a tube into a vein when normal feeding by mouth is not suitable.

TRIOMEL must only be used under medical supervision.

2. What you need to know before TRIOMEL 7 g/l nitrogen 1140 kcal/l with electrolytes, emulsion for infusion is administered

TRIOMEL 7 g/l nitrogen 1140 kcal/l with electrolytes, emulsion for infusion must not be used:

- In premature neonates, infants, and children less than 2 years old.
- If you are hypersensitive (allergic) to egg, soya-bean, peanut proteins, or corn/corn products (see also section “Warnings and precautions” below), or to any other ingredient of this medicine (listed in section 6).
- If your body has problems using certain amino acids.
- If you have an especially high level of fats in your blood.
- If you have hyperglycaemia (too much sugar in your blood).
- If you have an abnormally high amount of any of the electrolytes (sodium, potassium, magnesium, calcium, and/or phosphorus) in your blood.

In all cases, your doctor will base his/her decision on whether you should receive this medicine on factors such as your age, weight, and medical condition, together with the results of any test performed.

Warnings and precautions

Talk to your doctor or nurse before TRIOMEL is administered to you.

If you are given total parenteral nutrition (TPN) solutions too fast this may result in injury or death.

The infusion must be stopped immediately if any abnormal signs or symptoms of an allergic reaction (such as sweating, fever, chills, headache, skin rashes, or difficulty breathing) develop. This medicinal product contains soya-bean oil and egg phospholipids. Soya-bean and egg proteins may cause hypersensitivity reactions. Cross-allergic reactions between soya-bean and peanut proteins have been observed.

TRIOMEL contains glucose derived from corn, which may cause hypersensitivity reactions if you have allergy to corn or corn products (see section "TRIOMEL emulsion for infusion must not be used" above).

Difficulty breathing could also be a sign that small particles have formed, blocking blood vessels in the lungs (pulmonary vascular precipitates). If you experience any difficulty breathing, tell your doctor or nurse. They will decide a course of action to be taken.

The antibiotic named ceftriaxone must not be mixed or given simultaneously with any calcium containing solutions (including TRIOMEL) given to you by a drip into your vein.

These drugs must not be given to you together even via different infusion lines or different infusion sites.

However, you may be given TRIOMEL and ceftriaxone sequentially one after another if infusion lines at different sites are used or if the infusion lines are replaced or were thoroughly flushed with physiological salt solution between the infusions to avoid precipitation (formation of particles of ceftriaxone-calcium salt).

Certain medications and illnesses can increase the risk of developing infection or sepsis (bacteria in the blood). There is a particular risk of infection or sepsis when a tube (intravenous catheter) is placed in your vein. Your doctor will carefully watch you for any signs of infection. Patients who require parenteral nutrition (giving nutrition through a tube in your vein) may be more likely to develop infections from their medical conditions. Using aseptic ("germ-free") techniques when placing and caring for the catheter and when making the nutritional formula (TPN) can reduce the risk of infection.

If you are severely malnourished such that you need to receive feedings by vein, your doctor should start the treatment slowly. Also, your doctor should monitor you closely to prevent sudden changes in your fluid, vitamin, electrolyte and mineral levels.

The balance of water and salt in your body and metabolic disorders will be corrected before starting the infusion. Your doctor will monitor your condition while you receive this medicine and may change the dosage or give you additional nutrients, such as vitamins, electrolytes, and trace elements, if he/she feels they are appropriate.

Liver disorders including problems with the elimination of bile (cholestasis), fat storage (hepatic steatosis), fibrosis, possibly leading to hepatic failure, as well as cholecystitis and cholelithiasis have been reported in patients who take intravenous nutrition therapy. The cause of these disorders is thought to be due to multiple factors and may differ between patients. If you suffer from symptoms such as nausea, vomiting, abdominal pain, yellowing of the skin or eyes, consult your doctor in order to allow the identification of possible causative and contributory factors, and possible therapeutic and preventive measures.

Your doctor should be aware of:

- a severe kidney problem. You also must inform your doctor if you are on dialysis (artificial kidney) or if you have another form of blood cleaning treatment
- a severe liver problem
- a blood clotting problem
- adrenal glands that are not working properly (adrenal insufficiency). The adrenal glands are triangle-shaped glands located on top of your kidneys
- heart failure
- lung disease
- a build up of water in your body (hyperhydration)
- not enough water in your body (dehydration)
- high blood sugar (diabetes mellitus) that you are not being treated for
- a heart attack or shock due to a sudden heart failure
- a severe metabolic acidosis (when the blood is too acidic)
- a generalised infection (septicaemia)
- coma.

To check the effectiveness and ongoing safety of the administration, your doctor will perform clinical and laboratory tests while you are receiving this medicine. If you are given this medicine for several weeks, your blood will be monitored on a regular basis.

Reduced ability of the body to remove the fats contained in this medicine may result in a "fat overload syndrome" (See Section 4 – Possible Side Effects).

During the infusion if you notice pain, burning or swelling at the infusion site, or leakage of the infusion, tell your doctor or nurse. The administration will be stopped immediately and restarted in another vein.

If your blood sugar gets too high, your doctor should adjust the rate of TRIOMEL delivery or give you medication to control your blood sugar (insulin).

TRIOMEL may only be administered via a tube (catheter) into a large vein in your chest (central vein).

Children and adolescents

If your child is under 18 years old, special care will be taken to give him/her the correct dosage. Increased precautions will also be taken because of the greater sensitivity of children to the risk of infection. Vitamin and trace element supplementation is always required. Paediatric formulations must be used.

Other medicines and TRIOMEL

Tell your doctor if you are taking or using, have recently taken or used or might take or use any other medicines.

Simultaneous absorption of other medicinal products is not a contraindication, generally. If you take other medicinal products, with or without medical prescription, you should inform your doctor in advance to check compatibility.

Please tell your doctor if you are taking or receiving any of the following:

- Insulin
- Heparin

TRIOMEL must not be administered simultaneously with blood through the same infusion tubing.

TRIOMEL contains calcium. It should not be given together or through the same tube with the antibiotic ceftriaxone because particles may form. If the same device is used to give you successively these medicines, it should be thoroughly rinsed.

Due to the risk of precipitation, TRIOMEL should not be administered through the same infusion line or admixed together with the antibiotic ampicillin or the antiepileptic fosphenytoin.

The olive and soya-bean oils present in TRIOMEL contain vitamin K. This does not normally affect blood thinning medicines (anticoagulants) like coumarin. However, if you take anticoagulant medicines you should tell your doctor.

The lipids contained in this emulsion may interfere with the results of certain laboratory tests if the blood sample is taken before the lipids have been eliminated from your bloodstream (these are generally eliminated after a period of 5 to 6 hours without receiving lipids).

TRIOMEL contains potassium. Special care should be taken in patients taking diuretics, ACE inhibitors, angiotensin II receptor antagonists (drugs for high blood pressure), or immunosuppressants. These types of drugs may increase potassium levels in your blood.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before you are given this medicine.

There are no adequate experiences from the use of TRIOMEL in pregnant or breast-feeding women. TRIOMEL may be considered during pregnancy and breastfeeding, if necessary. TRIOMEL should only be given to pregnant or breast-feeding women after careful consideration.

Driving and using machines

Not relevant.

3. How TRIOMEL 7 g/l nitrogen 1140 kcal/l with electrolytes, emulsion for infusion will be used

Dosage

TRIOMEL should only be given in adults and children greater than 2 years of age.

It is an emulsion for infusion, to be administered via a tube (catheter) into a vein in your chest.

TRIOMEL should be at room temperature before use.

TRIOMEL is for single use only.

The infusion of 1 bag usually lasts between 12 and 24 hours.

Dosage – Adults

Your doctor will specify a flow rate corresponding to your needs and clinical condition.

The prescription may be continued for as long as it is needed, depending upon your clinical condition.

Dosage – Children greater than two years of age and adolescents

The doctor will decide the dose and for how long the medication will be given. This will depend on age, weight, height, medical condition and the ability of the body to break down and use the ingredients in TRIOMEL.

If you have been administered more TRIOMEL 7 g/l nitrogen 1140 kcal/l with electrolytes, emulsion for infusion than you should

If the dose given is too high or the infusion is too fast, the amino acid content may make your blood too acidic, and signs of hypervolaemia (increase of circulating blood volume) may occur. The glucose levels in your blood and urine may increase, hyperosmolar syndrome (excessive blood viscosity) may develop, and the lipid content may increase the level of triglycerides in your blood. Receiving an excessively fast infusion or a volume of TRIOMEL that is too large may cause nausea, vomiting, chills, headache, hot flush, excessive sweating (hyperhidrosis) and electrolyte disturbances. In such situations, the infusion must be stopped immediately.

In some severe cases, your doctor may have to give you temporary renal dialysis to help your kidneys eliminate the excess product.

To prevent these events occurring, your doctor will regularly monitor your condition and test your blood parameters.

If you have any further questions on the use of this product, ask your doctor.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you notice any changes in the way you feel during or after the treatment, tell your doctor or nurse right away.

The tests your doctor will perform while you are taking the medicine should minimise the risk of side effects.

If any abnormal signs or symptoms of an allergic reaction develop, such as sweating, fever, chills, headache, skin rashes, or breathing difficulties, the infusion should be stopped immediately.

The following side effects have been reported with TRIOMEL:

Frequency - Common: may affect up to 1 in 10 people

- Fast heart rate (tachycardia)
- Decreased appetite
- Increased level of fat in the blood (hypertriglyceridemia)
- Abdominal pain
- Diarrhoea
- Nausea
- Increased blood pressure (hypertension)

Frequency - Not known: frequency cannot be estimated from the available data

- Hypersensitivity reactions including sweating, fever, chills, headache, skin rash (erythematous, papular, pustular, macular, generalised rash), itching, hot flush, breathing difficulties
- Leakage of the infusion to the surrounding tissue (extravasation) which may result at infusion site level in pain, irritation, swelling/oedema, redness (erythema)/warmth, death of the tissue cells (skin necrosis) or blisters/vesicles, inflammation, thickening or constriction of the skin
- Vomiting

The following side effects have been reported with similar parenteral nutrition products:

Frequency - Very rare: may affect up to 1 in 10,000 people

- Reduced ability to remove the lipids (fat overload syndrome) associated with sudden and abrupt worsening of the patient's medical condition. The following signs of fat overload syndrome are usually reversible when the lipid emulsion infusion is stopped:
    - Fever
    - Reduction in red blood cells which can make the skin pale and cause weakness or breathlessness (anaemia)
    - Low white blood cell count, which can increase the risk of infection (leukopenia)
    - Low platelet count which can increase the risk of bruising and/or bleeding (thrombocytopenia)
    - Coagulation disorders which effect the ability of the blood to clot
    - High levels of fats in the blood (hyperlipidaemia)
    - Liver fatty infiltration (hepatomegaly)
    - Worsening liver function
    - Central nervous system manifestations (e.g. Coma).

Frequency - Not known: frequency cannot be estimated from the available data

- Allergic reactions
- Abnormal blood test results for liver function
- Problems with the elimination of bile (cholestasis)

- Increase in the size of the liver (hepatomegaly)
- Parenteral nutrition associated liver disease (see "Warnings and Precautions" in section 2)
- Icterus (jaundice)
- Decrease in the number of platelets (thrombocytopenia)
- Increased nitrogen levels in the blood (azotemia)
- Elevated liver enzymes
- Formation of small particles which may lead to blockage of blood vessels in the lungs (pulmonary vascular precipitates) resulting in pulmonary vascular embolism and difficulty breathing (respiratory distress).

Reporting of side effects

If you get any side effect, talk to your doctor or nurse. This includes any possible side effect not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

Malta
ADR Reporting
Website: www.medicinesauthority.gov.mt/adrportal

Republic of Ireland:
HPRA Pharmacovigilance,
Earlsfort Terrace,
IRE – Dublin 2.
Tel: +353 1 6764971,
Fax: +353 1 6762517,
Website: www.hpra.ie;
E-mail: medsafety@hpra.ie

United Kingdom:
Via the Yellow Card Scheme at:
www.mhra.gov.uk/yellowcard

5. How TRIOMEL 7 g/l nitrogen 1140 kcal/l with electrolytes, emulsion for infusion is stored

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date that is stated on the container and the outer packaging (MM/YYYY). The expiry date refers to the last day of that month.

Do not freeze.

Store in the overpouch.

Do not throw away medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What TRIOMEL 7 g/l nitrogen 1140 kcal/l with electrolytes, emulsion for infusion contains

The active substances for each bag of the reconstituted emulsion are 11.1% (corresponding to 11.1 g/100 mL) L-amino acid solution (alanine, arginine, glycine, histidine, isoleucine, leucine, lysine (as lysine acetate), methionine, phenylalanine, proline, serine, threonine, tryptophan, tyrosine, valine, aspartic acid, glutamic acid) with electrolytes (sodium, potassium, magnesium, phosphate, acetate, chloride), 20% (corresponding to 20 g/100 mL) lipid emulsion (refined olive oil and refined soya-bean oil), and 35% (corresponding to 35 g/100 mL) glucose solution (as glucose monohydrate) with calcium.

The other ingredients are:

Lipid emulsion compartment	Amino acid solution compartment	Glucose solution compartment
Purified egg phospholipids, glycerol, sodium oleate, sodium hydroxide (for pH adjustment), water for injection	Glacial acetic acid (for pH adjustment), water for injection	Hydrochloric acid (for pH adjustment), water for injection

What TRIOMEL 7 g/l nitrogen 1140 kcal/l with electrolytes, emulsion for infusion looks like and contents of the pack

TRIOMEL is an emulsion for infusion packaged in a 3-compartment bag. One compartment contains a lipid emulsion, another compartment an amino acid solution with electrolytes and the third compartment a glucose solution with calcium. These compartments are separated by nonpermanent seals. Before administration, the content of the compartments need to be mixed by rolling the bag onto itself, starting at the top of the bag until the peal seal is open.

Appearance prior to reconstitution:

- The amino acid and glucose solutions are clear, colourless, or slightly yellow.
- The lipid emulsion is homogenous with a milky appearance.

Appearance after reconstitution: homogeneous milk-like emulsion.

The 3-compartment bag is a multilayer plastic bag. The inner (contact) layer of the bag material is designed to be compatible with the constituents and authorised additives.
To prevent contact with oxygen contained in the air, the bag is packaged in an oxygen barrier overpouch with an oxygen absorber sachet.

Pack sizes

1,000 mL bag: 1 carton with 6 bags; 1 carton with 5 bags
1,500 mL bag: 1 carton with 4 bags; 1 carton with 5 bags
2,000 mL bag: 1 carton with 4 bags; 1 carton with 5 bags
1 bag of 1,000 mL, 1,500 mL and 2,000 mL

Not all pack sizes may be marketed.

Marketing Authorisation Holder

United Kingdom:
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Norfolk, IP24 3SE
United Kingdom

Republic of Ireland and Malta:
Baxter Holding B.V.
Kobaltweg 49,
3542CE Utrecht,
Netherlands

Manufacturer

BAXTER S.A.
BOULEVARD RENE BRANQUART, 80
7860 LESSINES
BELGIUM

This medicinal product is authorised in the Member States of the EEA under the following names:

France, Portugal, Estonia, Poland, Lithuania, Bulgaria, Romania, Latvia, Czech Republic, Belgium, Spain, Slovak Republic, The Netherlands, Luxemburg, Slovenia, Italy, Greece, Cyprus: OLIMEL N7E

In some countries it is registered under a different trade name, as described below:
Austria: ZentroOLIMEL 4,4 % mit Elektrolyten
Germany: **Olimel** 4,4% E
Denmark, Iceland, Sweden, Norway, Finland: Olimel N7E
The United Kingdom, Ireland, Malta: Triomel 7 g/l nitrogen 1140 kcal/l with electrolytes

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For information about TRIOMEL or to request this leaflet in formats such as audio or large print please contact the Marketing Authorisation Holder: Tel: +44 (0)1635 206345

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The following information is intended for healthcare professionals only:

TRIOMEL 7 g/l nitrogen 1140 kcal/l with electrolytes, emulsion for infusion

Pharmacotherapeutic group: Solutions for parenteral nutrition/combinations
ATC code: B05 BA10.

A. QUALITATIVE AND QUANTITATIVE COMPOSITION

TRIOMEL is presented in the form of a 3-compartment bag.

Each bag contains a glucose solution with calcium, a lipid emulsion and an amino acid solution with other electrolytes.

	Contents per bag		
	1,000 mL	**1,500 mL**	**2,000 mL**
35% Glucose solution (corresponding to 35 g/100 mL)	400 mL	600 mL	800 mL
11.1% Amino acid solution (corresponding to 11.1 g/100 mL)	400 mL	600 mL	800 mL
20% Lipid emulsion (corresponding to 20 g/100 mL)	200 mL	300 mL	400 mL

Composition of the reconstituted emulsion after mixing the contents of the 3 compartments:

Active substances	**1,000 mL**	**1,500 mL**	**2,000 mL**
Refined olive oil+ refined soya-bean oil[a]	40.00 g	60.00 g	80.00 g
Alanine	6.41 g	9.61 g	12.82 g
Arginine	4.34 g	6.51 g	8.68 g
Aspartic acid	1.28 g	1.92 g	2.56 g
Glutamic acid	2.21 g	3.32 g	4.42 g
Glycine	3.07 g	4.60 g	6.14 g
Histidine	2.64 g	3.97 g	5.29 g
Isoleucine	2.21 g	3.32 g	4.42 g
Leucine	3.07 g	4.60 g	6.14 g
Lysine (equivalent to lysine acetate)	3.48 g (4.88 g)	5.23 g (7.31 g)	6.97 g (9.75 g)
Methionine	2.21 g	3.32 g	4.42 g
Phenylalanine	3.07 g	4.60 g	6.14 g
Proline	2.64 g	3.97 g	5.29 g
Serine	1.75 g	2.62 g	3.50 g
Threonine	2.21 g	3.32 g	4.42 g
Tryptophan	0.74 g	1.10 g	1.47 g
Tyrosine	0.11 g	0.17 g	0.22 g
Valine	2.83 g	4.25 g	5.66 g
Sodium acetate, trihydrate	1.50 g	2.24 g	2.99 g
Sodium glycerophosphate, hydrated	3.67 g	5.51 g	7.34 g
Potassium chloride	2.24 g	3.35 g	4.47 g
Magnesium chloride, hexahydrate	0.81 g	1.22 g	1.62 g
Calcium chloride, dihydrate	0.52 g	0.77 g	1.03 g
Glucose (equivalent to glucose monohydrate)	140.00 g (154.00 g)	210.00 g (231.00 g)	280.00 g (308.00 g)

a: Mixture of refined olive oil (approximately 80%) and refined soya-bean oil (approximately 20%) corresponding to a ratio essential fatty acids/total fatty acids of 20%.

The excipients are:

Lipid emulsion compartment	Amino acid solution with electrolytes compartment	Glucose solution with calcium compartment
Purified egg phospholipids, glycerol, sodium oleate, sodium hydroxide (for pH adjustment), water for injection	Glacial acetic acid (for pH adjustment), water for injection	Hydrochloric acid (for pH adjustment), water for injection

Nutritional intakes of reconstituted emulsion for each of the bag sizes:

	1,000 mL	**1,500 mL**	**2,000 mL**
Lipids	40 g	60 g	80 g
Amino acids	44.3 g	66.4 g	88.6 g
Nitrogen	7.0 g	10.5 g	14.0 g
Glucose	140.0 g	210.0 g	280.0 g
Energy:			
Total calories approx.	1,140 kcal	1,710 kcal	2,270 kcal
Non-protein calories.	960 kcal	1,440 kcal	1,920 kcal
Glucose calories	560 kcal	840 kcal	1,120 kcal
Lipid calories[a]	400 kcal	600 kcal	800 kcal
Non-protein calories / nitrogen ratio	137 kcal/g	137 kcal/g	137 kcal/g
Glucose /lipid calories ratio	58/42	58/42	58/42
Lipid /total calories	35%	35%	35%
Electrolytes:			
Sodium	35.0 mmol	52.5 mmol	70.0 mmol
Potassium	30.0 mmol	45.0 mmol	60.0 mmol
Magnesium	4.0 mmol	6.0 mmol	8.0 mmol
Calcium	3.5 mmol	5.3 mmol	7.0 mmol
Phosphate[b]	15.0 mmol	22.5 mmol	30.0 mmol
Acetate	45 mmol	67 mmol	89 mmol
Chloride	45 mmol	68 mmol	90 mmol
pH	6.4	6.4	6.4
Osmolarity	1,360 mosm/L	1,360 mosm/L	1,360 mosm/L

a: Includes calories from purified egg phospholipids
b: Includes phosphate provided by the lipid emulsion

B. POSOLOGY AND METHOD OF ADMINISTRATION

Posology

TRIOMEL is not recommended for use in children less than 2 years of age due to inadequate composition and volume (see sections 4.4; 5.1 and 5.2 of the SmPC).

The maximum daily dose mentioned below should not be exceeded. Due to the static composition of the multi-chamber bag, the ability to simultaneously meet all nutrient needs of the patient may not be possible. Clinical situations may exist where patients require amounts of nutrients varying from the composition of the static bag. In this situation any volume (dose) adjustments must take into consideration the resultant effect this will have on the dosing of all other nutrient components of TRIOMEL.

In adults

The dosage depends on the patient's energy expenditure, clinical status, body weight, and the ability to metabolise the constituents of TRIOMEL, as well as additional energy or proteins provided orally/ enterally; therefore, the bag size should be chosen accordingly.
The average daily requirements are:

- 0.16 to 0.35 g nitrogen /kg body weight (1 to 2 g of amino acids/kg), depending on the patient's nutritional status and degree of catabolic stress,
- 20 to 40 kcal/kg,
- 20 to 40 mL fluid /kg, or 1 to 1.5 mL per expended kcal.

For TRIOMEL, the maximal daily dose is defined by total caloric intake, 40 kcal/kg provided in a volume of 35 mL/kg, corresponding to 1.5 g/kg amino acids, 4.9 g/kg glucose, 1.4 g/kg lipids, 1.2 mmol/kg sodium, and 1.1 mmol/kg potassium. For a 70 kg patient, this would be equivalent to 2,450 mL TRIOMEL per day, resulting in an intake of 108 g amino acids, 343 g glucose, and 98 g lipids (i.e., 2,352 non-protein kcal and 2,793 total kcal).

Normally, the flow rate must be increased gradually during the first hour and then be adjusted to take into account the dose being administered, the daily volume intake, and the duration of the infusion.

For TRIOMEL, the maximal infusion rate is 1.7 mL/kg/hour, corresponding to 0.08 g/kg/hour amino acids, 0.24 g/kg/hour glucose, and 0.07 g/kg/hour lipids.

In children greater than 2 years of age and adolescents

There have been no studies performed in the paediatric population.

The dosage depends on the patient's energy expenditure, clinical status, body weight, and the ability to metabolise constituents of TRIOMEL, as well as additional energy or proteins given orally/enterally; therefore, the bag size should be chosen accordingly.

In addition, daily fluid, nitrogen, and energy requirements continuously decrease with age. Two groups, ages 2 to 11 years and 12 to 18 years, are considered.

For TRIOMEL 7 g/l nitrogen 1140 kcal/l with electrolytes, in both age groups, the magnesium concentration is the limiting factor for daily dose. In both age groups, the glucose concentration is the limiting factor for hourly rate. The resulting intakes are displayed below:

Constituent	2 to 11 years		12 to 18 years	
	Recommended[a]	TRIOMEL 7 g/l nitrogen 1140 kcal/l with electrolytes Max Vol	Recommended[a]	TRIOMEL 7 g/l nitrogen 1140 kcal/l with electrolytes Max Vol
Maximum Daily Dose				
Fluids (mL/kg/d)	60 – 120	25	50 – 80	25
Amino acids (g/kg/d)	1 – 2 (up to 2.5)	1.1	1 – 2	1.1
Glucose (g/kg/d)	1.4-8.6	3.5	0.7 - 5.8	3.5
Lipids (g/kg/d)	0.5 –3	1.0	0.5 – 2 (up to 3)	1.0
Total energy (kcal/kg/d)	30 – 75	28.5	20 – 55	28.5
Maximum Hourly Rate				
TRIOMEL (mL/kg/h)		2.6		1.7
Amino acids (g/kg/h)	0.20	0.11	0.12	0.08
Glucose (g/kg/h)	0.36	0.36	0.24	0.24
Lipids (g/kg/h)	0.13	0.10	0.13	0.07

a: Recommended values from 2018 ESPGHAN/ESPEN/ESPR Guidelines

Normally, the flow rate must be increased gradually during the first hour and then be adjusted to take into account the dose being administered, the daily volume intake, and the duration of the infusion.

In general, it is recommended to start the infusion for small children with low daily dose and gradually increase it up to the maximal dosage (see above).

Method and duration of administration

For single use only.

It is recommended that, after opening the bag, the contents are used immediately and not stored for subsequent infusion.

After reconstitution, the mixture is homogenous with a milky appearance.

For instructions for preparation and handling of the emulsion for infusion, see section 6.6 of the SmPC.

Due to its high osmolarity, TRIOMEL can only be administered through a central vein.

The recommended duration of infusion for a parenteral nutrition bag is between 12 and 24 hours.

Treatment with parenteral nutrition may be continued for as long as required by the patient's clinical conditions.

C. INCOMPATIBILITIES

Do not add other medicinal products or substances to any components of the bag or to the reconstituted emulsion without first confirming their compatibility and the stability of the resulting preparation (in particular, the stability of the lipid emulsion).

Incompatibilities may be produced, for example, by excessive acidity (low pH) or inappropriate content of divalent cations (Ca^{2+} and Mg^{2+}), which may destabilize the lipid emulsion.

As with any parenteral nutrition admixture, calcium and phosphate ratios must be considered. Excess addition of calcium and phosphate, especially in the form of mineral salts, may result in the formation of calcium phosphate precipitates.

TRIOMEL contains calcium ions which pose additional risk of coagulation precipitated in citrate anticoagulated/preserved blood or components.

Ceftriaxone must not be mixed or administered simultaneously with intravenous calcium-containing solutions, including TRIOMEL, through the same infusion line (e.g., via Y-connector) because of the risk of precipitation of ceftriaxone-calcium salt (see section 4.4 and 4.5 of the SmPC).

Ceftriaxone and calcium-containing solutions may be administered sequentially one after another if infusion lines at different sites are used or if the infusion lines are replaced or thoroughly flushed between infusions with physiological salt-solution to avoid precipitation.

Due to the risk of precipitation, TRIOMEL should not be administered through the same infusion line or admixed together with ampicillin or fosphenytoin.

Check compatibility with solutions administered simultaneously through the same administration set, catheter, or cannula.

Do not administer before, simultaneously with, or after blood through the same equipment because of the risk of pseudoagglutination.

D. SPECIAL PRECAUTIONS FOR DISPOSAL AND OTHER HANDLING

An overview of the preparation steps for the administration of TRIOMEL are provided in Figure 1.

To open

Remove the protective overpouch.

Discard the oxygen absorber sachet.

Confirm the integrity of the bag and of the nonpermanent seals. Use only if the bag is not damaged; if the nonpermanent seals are intact (i.e., no mixture of the contents of the 3 compartments); if the amino acid solution and the glucose solution are clear, colourless, or slightly yellow, and practically free of visible particles; and if the lipid emulsion is a homogeneous liquid with a milky appearance.

Mixing the solutions and the emulsion

Ensure that the product is at room temperature when breaking the nonpermanent seals.

Manually roll the bag onto itself, starting at the top of the bag (hanger end). The nonpermanent seals will disappear from the side near the inlets. Continue to roll the bag until the seals are open along approximately half of their length.

Mix by inverting the bag at least 3 times.

After reconstitution, the mixture is a homogeneous emulsion with a milky appearance.

Additions

The capacity of the bag is sufficient to enable additions such as vitamins, electrolytes, and trace elements.

Any additions (including vitamins) may be made into the reconstituted mixture (after the nonpermanent seals have been opened and after the contents of the 3 compartments have been mixed).

Vitamins may also be added into the glucose compartment before the mixture is reconstituted (before opening the nonpermanent seals and before mixing the 3 compartments).

When making additions to formulations containing electrolytes, the amount of electrolytes already present in the bag should be taken into account.
Additions must be performed by qualified personnel under aseptic conditions.

TRIOMEL may be supplemented with electrolytes according to the table below:

	Per 1,000 mL		
	Included level	**Maximal further addition**	**Maximal total level**
Sodium	35 mmol	115 mmol	150 mmol
Potassium	30 mmol	120 mmol	150 mmol
Magnesium	4.0 mmol	1.6 mmol	5.6 mmol
Calcium	3.5 mmol	1.5 (0.0[a]) mmol	5.0 (3.5[a]) mmol
Inorganic Phosphate	0 mmol	3.0 mmol	3.0 mmol
Organic Phosphate	15 mmol[b]	10 mmol	25 mmol[b]

a: Value corresponding to the addition of inorganic phosphate.
b: Including phosphate provided by the lipid emulsion.

Trace elements and vitamins:

Stability has been demonstrated with commercially-available preparations of vitamins and trace elements (containing up to 1 mg of iron).

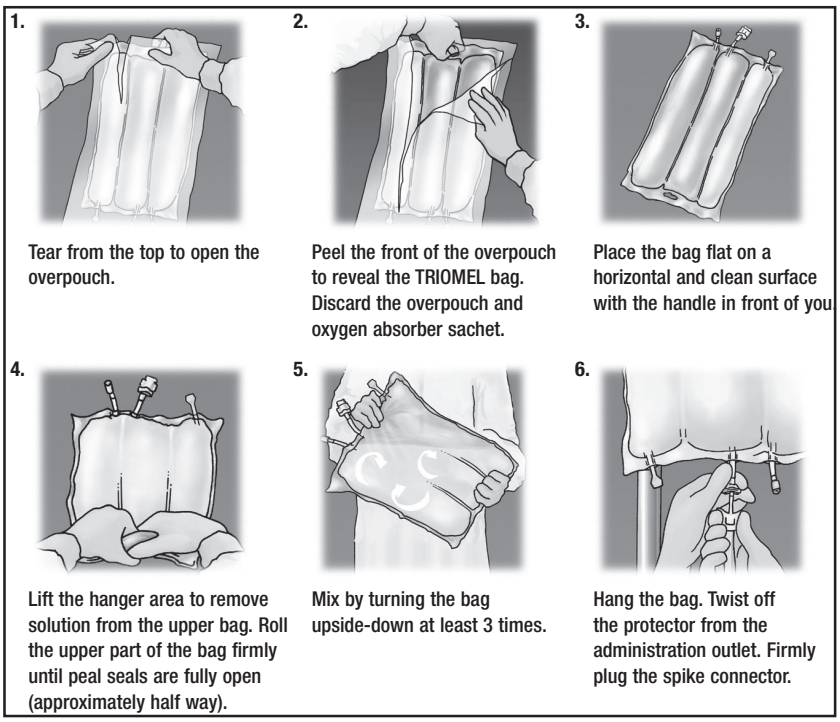
Compatibility for other additives is available upon request.

To perform an addition:
- Aseptic conditions must be observed.
- Prepare the injection site of the bag.
- Puncture the injection site and inject the additives using an injection needle or a reconstitution device.
- Mix content of the bag and the additives.

Preparation of the infusion

Aseptic conditions must be observed.
Suspend the bag.
Remove the plastic protector from the administration outlet.
Firmly insert the spike of the infusion set into the administration outlet.

Figure 1: Preparation steps for the administration of TRIOMEL



Administration

For single use only.

Only administer the product after the nonpermanent seals between the 3 compartments have been broken and the contents of the 3 compartments have been mixed.

Ensure that the final emulsion for infusion does not show any evidence of phase separation.

After opening the bag, the contents must be used immediately. The opened bag must never be stored for a subsequent infusion. Do not reconnect any partially used-bag.

Do not connect bags in series in order to avoid the possibility of air embolism due to gas contained in the primary bag.

Any unused product or waste material and all necessary devices must be discarded.

Extravasation

Catheter site should be monitored regularly to identify signs of extravasation.

If extravasation occurs, the administration should be stopped immediately, keeping the inserted catheter or cannula in place for immediate management of the patient. If possible, aspiration should be performed through the inserted catheter/cannula, in order to reduce the amount of fluid present in the tissues before removing the catheter/cannula.

Depending on the extravasated product (including the product(s) being mixed with TRIOMEL, if applicable) and the stage/extend of any injury, appropriate specific measures should be taken. Options for management may include non-pharmacologic, pharmacologic and/or surgical intervention. In case of large extravasation, plastic surgeon advice should be sought within the first 72 hours.

The extravasation site should be monitored at least every 4 hours during the 24 first hours, then once daily.

The infusion should not be restarted in the same central vein.