

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

TRIOMEL N7-960,

TRIOMEL N9-840

(Emulsion for infusion)

Refined olive oil + refined soya-bean oil, alanine, arginine, aspartic acid, glutamic acid, glycine, histidine, isoleucine, leucine, lysine acetate (equivalent to lysine), methionine, phenylalanine, proline, serine, threonine, tryptophan, tyrosine, valine, glucose monohydrate (equivalent to glucose anhydrous)

Read all of this leaflet carefully before you are given TRIOMEL.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- TRIOMEL has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What TRIOMEL is and what it is used for

2. What you need to know before you are administered TRIOMEL
3. How to receive TRIOMEL
4. Possible side effects
5. How to store TRIOMEL
6. Contents of the pack and other information

1. What TRIOMEL is and what it is used for

TRIOMEL is an emulsion for infusion.

TRIOMEL is used to provide nutrition in adults and children greater than two 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 you receive TRIOMEL

Do not receive TRIOMEL, emulsion for infusion in the following cases:

- For premature neonates, infants and children less than 2 years old.
- If you are hypersensitive (allergic) to egg proteins, soybean, peanuts or to any other ingredient.
- If you have a severe kidney problem and you are not on dialysis or another form of blood filtration treatment.
- If your body has problems using certain amino acids e.g. phenylketonuria
- If you have especially high level of fats in your blood.

- If you have severe hyperglycaemia (too much sugar in your blood)

Treatment with TRIOMEL is not suitable if you have:

- Acute pulmonary oedema (infiltration of serum into the lung tissue), hyperhydration (accumulation of water), heart failure, dehydration, or in unstable situation such as those following severe injuries, untreated diabetes mellitus, shock due to a sudden heart failure, heart attack, severe metabolic acidosis (when the blood is excessively acid), septicaemia (generalised infection) and coma.

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

Warnings and precautions

Take special care with TRIOMEL in the following instances:

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

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.

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.

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 TRIOMEL and may change the dosage or give you additional nutrients such as vitamins, electrolytes and trace elements if he/she feels it is appropriate.

Caution should be exercised in administering TRIOMEL to patients with liver or kidney problems, blood clotting problems, anaemia, increased serum osmolarity, adrenal insufficiency, heart failure, diabetes, high cholesterol or pulmonary dysfunction.

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.

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

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).

Other medicines and TRIOMEL

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

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

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

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Driving and using machines

TRIOMEL is not expected to affect your ability to drive or use machines.

3. How to receive TRIOMEL

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

TRIOMEL may only be administered via a plastic tube into a large vein.

Dosage – Adults

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

Dosage – Children greater than two years of age and adolescents

Your doctor will decide the dose the child will need and for how long it will be given. This will depend on age, weight and height, clinical condition, daily fluid volume, energy and nitrogen requirements.

If you receive more TRIOMEL than you should:

Since a healthcare professional will administer this medicine, he/she will control the dosage. However, in the event of overdose your doctor will manage the overdose.

4. Possible side effects

TRIOMEL, emulsion for infusion can cause side effects.

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

If any abnormal signs or symptoms of an allergic reaction develop, such as sweating, fever, shivering, headache, skin rashes or breathing difficulties, the infusion will 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)
- Loss of appetite (anorexia)
- Increased level of fat in the blood (hypertriglyceridemia)
- Abdominal pain
- Diarrhea
- Nausea
- Increased blood pressure (hypertension)

Frequency - Not known:

- 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

Other side effects of unknown frequency are:

- Vomiting
- Rash
- Fever
- Chills
- Abnormal blood test results for liver function.
- Increase in the size of the liver (hepatomegaly).
- Icterus (jaundice).
- Decrease in the number of platelets.
- Problems with the elimination of bile (cholestasis)
- 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).
- Reduced ability to remove the lipids contained in TRIOMEL may result in a "fat overload syndrome" which may be caused by overdose but may also occur at the start of an infusion, even according to instructions, and is associated with a sudden deterioration in the patient's clinical condition. It is characterised by excessive lipids in blood (hyperlipidaemia), fever, liver fatty infiltration, increase of liver size (hepatomegaly), anaemia, a fall in white blood cells and blood platelets, problem with your blood clotting and coma. All of these symptoms are usually reversible when the lipid emulsion infusion is stopped.

If any side effect gets serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

Not all side-effects reported for TRIOMEL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications:

<https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of TRIOMEL.

For reporting of side effects directly to the HCR, contact +27 11 635 0134 or email Adcock.aereports@adcock.com

5. How to store TRIOMEL

Before Reconstitution:

Store at or below 30 °C. Do not freeze. Store in the overpouch. Keep container in the outer carton.

After Reconstitution:

It is recommended that the product be used immediately after the peel seals have been broken and any unused portion of the reconstituted product must be discarded in accordance with local requirements.

The reconstituted emulsion, is stable for a maximum of 7 days at between 2 °C to 8 °C followed by a maximum of 48 hours at temperatures not exceeding 25 °C.

After addition of supplements (electrolytes, organic phosphates, trace elements, vitamins):

For specific admixtures, chemical and physical in-use stability has been demonstrated for 7 days at 2 °C to 8 °C followed by 48 hours at or below 25 °C. From a microbiological point of view, any admixture should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 °C to 8 °C, unless addition of supplements has taken place in controlled and validated aseptic conditions.

Do not receive TRIOMEL after the expiry date stated on the container.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

What TRIOMEL contains

Per 1 litre Bag of solution

Active Substances	Lipid emulsion compartment (200 ml)		Amino Acid solution compartment (400 ml)		Glucose solution compartment (400 ml)	
	N7-960	N9-840	N7-960	N9-840	N7-960	N9-840
Refined Olive Oil + Refined Soya-bean Oil*	40 g	40 g				
Alanine			6,41 g	8,24 g		
Arginine			4,34 g	5,58 g		
Aspartic acid			1,28 g	1,65 g		
Glutamic acid			2,21 g	2,84 g		
Glycine			3,07 g	3,95 g		
Histidine			2,64 g	3,40 g		
Isoleucine			2,21 g	2,84 g		
Leucine			3,07 g	3,95 g		

Lysine acetate <i>(equiv to Lysine)</i>			4,88 g 3,48 g	6,32 g 4,48 g		
Methionine			2,21 g	2,84 g		
Phenylalanine			3,07 g	3,95 g		
Proline			2,64 g	3,40 g		
Serine			1,75 g	2,25 g		
Threonine			2,21 g	2,84 g		
Tryptophan			0,74 g	0,95 g		
Tyrosine			0,11 g	0,15 g		
Valine			2,83 g	3,64 g		
Glucose Monohydrate <i>(equiv to glucose anhydrous)</i>					154 g 140 g	121,0 g 110,0 g

* A mixture of refined olive oil (approximately 80 % m/v) and refined soya-bean oil (approximately 20 % m/v), is calculated to reach an essential fatty acids content of 20 % of total fatty acids.

After the contents of the three compartments have been mixed, the ternary mixture for each of the bag presentations provides the following:

Per bag	1 litre		1,5 litre		2 litre	
	N7-960	N9-840	N7-960	N9-840	N7-960	N9-840
Nitrogen (g)	7,0	9,0	10,5	13,5	14,0	18,0
Amino Acids (g)	44,3	56,9	66,4	85,4	88,6	113,9
Glucose (g)	140	110	210	165	280	220
Lipids (g)	40	40	60	60	80	80
Energy:						

Total calories (Kcal)	1140	1070	1710	1600	2270	2140	
Non-protein calories (Kcal)	960	840	1440	1260	1920	1680	
Glucose calories (Kcal)	560	440	840	660	1120	880	
Lipid calories (Kcal)**	400	400	600	600	800	800	
Non-protein calories/nitro gen ratio (Kcal/g)	137	93	137	93	137	93	
Glucose/lipid calories ratio	58 / 42	52 / 48	58 / 42	52 / 48	58 / 42	52 / 48	

Lipid/total calories (%)	35	37	35	37	35	37
<i>Electrolytes:</i>						
Phosphate (mmol)**	3,0	3,0	4,5	4,5	6,0	6,0
Acetate (mmol)	31	40	46	60	62	80
pH	6,4	6,4	6,4	6,4	6,4	6,4
Osmolarity (mosm/l)	1220	1170	1220	1170	1220	1170

**Includes calories from purified egg phosphatides

*** Includes phosphate provided by the lipid emulsion

The active substances are refined olive oil, refined soya-bean oil, alanine, arginine, aspartic acid, glutamic acid, glycine, histidine, isoleucine, leucine, lysine acetate (equivalent to lysine), methionine, phenylalanine, proline, serine, threonine, tryptophan, tyrosine, valine, glucose monohydrate (equivalent to glucose anhydrous).

The other ingredients are purified egg phosphatide, glycerol, sodium oleate, water for injection, glacial acetic acid (for pH adjustment), hydrochloric acid (for pH adjustment) and sodium hydroxide (for pH adjustment).

What TRIOMEL looks like and contents of the pack

Identification prior to reconstitution:

The lipid compartment contains the lipid emulsion which is a homogenous liquid with a milky appearance.

The amino acids and glucose compartments consist of solutions which are clear and colourless or slightly yellow and practically free from particles.

Identification after reconstitution:

Homogenous liquid with a milky appearance

TRIOMEL is packed into a three-compartment bag. The triple-compartment bag is a multi-layer, clear and colourless plastic container packaged into an overpouch (silver, aluminium

foil, or clear, colourless laminated plastic). The inner (contact) layer of the bag material is made up of blend of polyolefinic copolymers and is compatible with amino acid solutions, glucose solutions, and lipid emulsions. Other layers are made of polyethylene vinyl acetate (EVA) and of copolyester. One compartment contains a lipid emulsion, the second compartment contains an amino acid solution and the third compartment contains a glucose solution.

The glucose compartment is fitted with an injection site to be used for addition of supplements.

The amino acids compartment is fitted with an administration site for insertion of the spike of the infusion set.

The bag is packaged in an oxygen barrier overpouch with an oxygen absorber sachet.

TRIOMEL is available in pack sizes of 1 l, 1,5 l and 2 l.

Holder of Certificate of Registration

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