

XXXXXX XXX

Baxter

CONTROLLED MEDICINE

Indication:

- Intended for parenteral nutrition for adults and children above 2 years of age when oral or enteral nutrition is impossible, insufficient, or contraindicated.
- Sterile. For single use only.
- Read carefully the package leaflet before use.
- Keep out of reach and sight of children.
- Jauhi daripada kanak-kanak.
- Do not freeze.
- Do not connect in series.
- Discard any unused solution, waste material and all necessary disposable devices.
- Do not infuse before, simultaneously or after administration of blood through the same equipment.
- Use only if the amino acids and glucose solutions are clear, the lipid emulsion and the final mixture after reconstitution are homogenous and with a milky appearance and the container undamaged.

1000

- Do not infuse without opening the seals and mixing the contents of the three compartments.

500

Manufactured by:

Baxter SA,
80, Bvd Rene Branquart,
7860 Lessines, Belgium

Product Registration Holder

Baxter Healthcare (M) Sdn Bhd
B-21-3A, The Ascent, Paradigm,
1, Jin SS7/26A, 47301 PJ,
Selangor, Malaysia.

MAL No : MAL16085022AZ

OLIMEL

N9E

Emulsion for Infusion

For central intravenous administration

1000ml of the final mixture provides the following:

Total calories approx.	1070 kcal
Non-protein calories approx.	840 kcal
Nitrogen	9.0 g
Non-protein calories / nitrogen ratio	93 kcal/g
Glucose	110.0g
Lipids	40g
Glucose / lipid calories ratio	52/48
Amino acids	56.9g
Glucose calories	440 kcal
Lipid calories approx (¹)	400 kcal
Lipid / total calories	37%
Electrolytes:	
Sodium	35.0 mmol
Potassium	30.0 mmol
Magnesium	4.0 mmol
Calcium	3.5 mmol
Phosphate (²)	15.0 mmol
Acetate	54 mmol
Chloride	45 mmol
pH approx.	6.4
Osmolarity approx.	1310 mosm/l
(1) Mixture of refined olive oil (approximately 80%) and refined soybean oil (approximately 20%) corresponding to a ratio essential fatty acids/ total fatty acids of 20%	
(2) Includes calories from purified egg phosphatides	
(3) Includes phosphate provided by the lipid emulsion	

XXXXXX XXX

EXP:

MFG:

Bag

Nitrogen g

Total Kcal

Non-protein calories Kcal

9

1070

840

1000 ml

Formula for 1000 ml after mixing:

Refined olive oil + refined soybean oil 40.00 g(¹), Alanine 8.24g, Arginine 5.58g, Aspartic acid 1.65g, Glutamic acid 2.84 g, Glycine 3.95g, Histidine 3.40g, Isoleucine 2.84g, Leucine 3.95 g, Lysine 4.48g (equivalent to Lysine acetate 6.32g), Methionine 2.84g, Phenylalanine 3.95g, Proline 3.40g, Serine 2.25g, Threonine 2.84g, Tryptophan 0.95g, Tyrosine 0.15g, Valine 3.64g, Sodium acetate trihydrate 1.5 g, Sodium glycerophosphate hydrated 3.67g, Potassium chloride 2.24 g, Magnesium chloride hexahydrate 0.81g, Calcium chloride dihydrate 0.52g, Glucose anhydrous 110.00g (equivalent to Glucose monohydrate 121.00g)

Excipients:

Lipid emulsion compartment:

Purified egg phosphatide (Chicken source), Glycerol, Sodium oleate, Sodium hydroxide (for pH adjustment),

Water for injection.

Compartment of amino-acid solution with electrolytes:

Glacial acetic acid (for pH adjustment),

Water for injection.

Compartment of glucose solution with calcium:

Hydrochloric acid (for pH adjustment),

Water for injection.

After reconstitution: Emulsion for Infusion

1000 ml in a 3 compartment bag

Glucose solution 27.5% : 400 ml

Amino acid solution 14.2% : 400 ml

Lipid emulsion 20% : 200 ml

Storage :

Store in the overpouch.

Store at temperature not exceeding 30°C.

Storage after reconstitution:

- Only administer the product after the non-permanent seals between the three compartments have been broken and the contents of the three compartments have been mixed.
- After reconstitution, immediately administer the product.
- However, the stability of the reconstituted emulsion has been demonstrated for 7 days (between 2°C and 8°C) followed by 48 hours at temperature not exceeding 30°C.

Storage after addition of supplements

(electrolytes, trace elements and vitamins):

- For specific admixtures, in-use stability has been demonstrated for 7 days (between 2°C and 8°C) followed by 48 hours at temperature not exceeding 25°C.
- From a microbiological point of view, any admixture should be used immediately. (See enclosed leaflet).

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RECYCLE
SYMBOL

LOT :

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- Do not infuse before, simultaneously or after administration of blood through the same equipment.
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1500

1000

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MAL No : MALxxxxxxx

OLIMEL

N9E

Emulsion for Infusion

For central intravenous administration

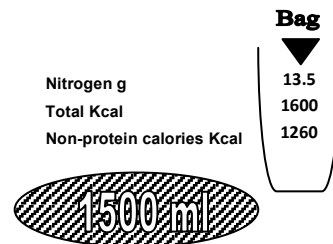
1500ml of the final mixture provides the following:

Total calories approx	1600 kcal
Non-protein calories approx.	1260 kcal
Nitrogen	13.5 g
Non-protein calories / nitrogen ratio	93 kcal/g
Glucose	165.0g
Lipids	60g
Glucose / lipid calories ratio	52/48
Amino acids	85.4g
Glucose calories	660 kcal
Lipid calories approx (°)	600 kcal
Lipid / total calories	37%
Electrolytes:	
Sodium	52.5 mmol
Potassium	45.0 mmol
Magnesium	6.0 mmol
Calcium	5.3 mmol
Phosphate (°)	22.5 mmol
Acetate	80 mmol
Chloride	68 mmol
pH approx.	6.4
Osmolarity approx.	1310 mosm/l
(1) Mixture of refined olive oil (approximately 80%) and refined soybean oil (approximately 20%) corresponding to a ratio essential fatty acids/ total fatty acids of 20%	
(2) Includes calories from purified egg phosphatides	
(3) Includes phosphate provided by the lipid emulsion	

XXXXXX XXX

MFG:

EXP:



Formula for 1500 ml after mixing:

Refined olive oil + refined soybean oil 60.00 g(°),
Alanine 12.36g, Arginine 8.37g, Aspartic acid 2.47g,
Glutamic acid 4.27g, Glycine 5.92g, Histidine
5.09g, Isoleucine 4.27g, Leucine 5.92g, Lysine
6.72g (equivalent to Lysine acetate 9.48g),
Methionine 4.27g, Phenylalanine 5.92g, Proline
5.09g, Serine 3.37g, Threonine 4.27g, Tryptophan
1.42g, Tyrosine 0.22g, Valine 5.47g, Sodium
acetate trihydrate 2.24g, Sodium glycerophosphate
hydrated 5.51g, Potassium chloride 3.35g,
Magnesium chloride hexahydrate 1.22g, Calcium
chloride dihydrate 0.77g, Glucose anhydrous
165.00g (equivalent to Glucose monohydrate
181.50g).

Excipients:

Lipid emulsion compartment:

Purified egg phosphatide (Chicken source), Glycerol,
Sodium oleate, Sodium hydroxide (for pH
adjustment),
Water for injection.

Compartment of amino-acid solution with electrolytes:

Glacial acetic acid (for pH adjustment),
Water for injection.

Compartment of glucose solution with calcium:

Hydrochloric acid (for pH adjustment),
Water for injection.

After reconstitution: Emulsion for Infusion

1500 ml in a 3 compartment bag
Glucose solution 27.5% : 600 ml
Amino acid solution 14.2% : 600 ml
Lipid emulsion 20% : 300 ml

Storage :

Store in the overpouch.

Store at temperature not exceeding 30°C.

Storage after reconstitution:

- Only administer the product after the non-permanent seals between the three compartments have been broken and the contents of the three compartments have been mixed.
- After reconstitution, immediately administer the product.
- However, the stability of the reconstituted emulsion has been demonstrated for 7 days (between 2°C and 8°C) followed by 48 hours at temperature not exceeding 30°C.

Storage after addition of supplements

(electrolytes, trace elements and vitamins):

- For specific admixtures, in-use stability has been demonstrated for 7 days (between 2°C and 8°C) followed by 48 hours at temperature not exceeding 25°C.
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- Use only if the amino acids and glucose solutions are clear, the lipid emulsion and the final mixture after reconstitution are homogenous and with a milky appearance and the container undamaged.
- Do not infuse without opening the seals and mixing the contents of the three compartments.

2000

1500

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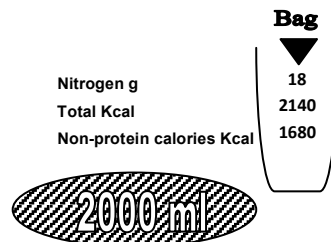
2000ml of the final mixture provides the following:

Total calories approx	2140 kcal
Non-protein calories approx.	1680 kcal
Nitrogen	18.0 g
Non-protein calories / nitrogen ratio	93 kcal/g
Glucose	220.0g
Lipids	80g
Glucose / lipid calories ratio	52/48
Amino acids	113.9g
Glucose calories	880 kcal
Lipid calories approx (°)	800 kcal
Lipid / total calories	37%
Electrolytes:	
Sodium	70.0 mmol
Potassium	60.0 mmol
Magnesium	8.0 mmol
Calcium	7.0 mmol
Phosphate (°)	30.0 mmol
Acetate	107 mmol
Chloride	90 mmol
pH approx.	6.4
Osmolarity approx.	1310 mosm/l
(1) Mixture of refined olive oil approximately 80% and refined soybean oil (approximately 20%) corresponding to a ratio essential fatty acids/ total fatty acids of 20%	
(2) Includes calories from purified egg phosphatides	
(3) Includes phosphate provided by the lipid emulsion	

XXXXXX XXX

MFG:

EXP:



Formula for 2000 ml after mixing:

Refined olive oil + refined soybean oil 80.00 g(°),
Alanine 16.48g, Arginine 11.16g, Aspartic acid 3.30g, Glutamic acid 5.69g, Glycine 7.90g, Histidine 6.79g, Isoleucine 5.69g, Leucine 7.90g, Lysine 8.96g (equivalent to Lysine acetate 12.64g), Methionine 5.69g, Phenylalanine 7.90g, Proline 6.79g, Serine 4.50g, Threonine 5.69g, Tryptophan 1.90g, Tyrosine 0.30g, Valine 7.29g, Sodium acetate trihydrate 2.99g, Sodium glycerophosphate hydrated 7.34g, Potassium chloride 4.47g, Magnesium chloride hexahydrate 1.62g, Calcium chloride dihydrate 1.03g, Glucose anhydrous 220.00g (equivalent to Glucose monohydrate 242.00g)

Excipients:

Lipid emulsion compartment:

Purified egg phosphatide (Chicken source), Glycerol, Sodium oleate, Sodium hydroxide (for pH adjustment),
Water for injection.

Compartment of amino-acid solution with electrolytes:

Glacial acetic acid (for pH adjustment),
Water for injection.

Compartment of glucose solution with calcium:

Hydrochloric acid (for pH adjustment),
Water for injection.

After reconstitution: Emulsion for Infusion

2000 ml in a 3 compartment bag
Glucose solution 27.5% : 800 ml
Amino acid solution 14.2% : 800 ml
Lipid emulsion 20% : 400 ml

Storage :

Store in the overpouch.

Store at temperature not exceeding 30°C.

Storage after reconstitution:

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