# OLIMEL N9E, emulsion for infusion

**(Glucose : Amino Acid : Lipid = 27.5% : 14.2% : 20%)**

## QUALITATIVE AND QUANTITATIVE COMPOSITION

OLIMEL 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.

| | **Content per bag (1000ml)** |
|---|---|
| 27.5 % Glucose solution (corresponding to 27.5 g/100 ml) | 400 ml |
| 14.2 % Amino acid solution (corresponding to 14.2 g/100 ml) | 400 ml |
| 20 % Lipid emulsion (corresponding to 20 g/100 ml) | 200 ml |

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

| **Active substances** | **Content per bag (1000ml)** |
|---|---|
| Refined olive oil+ refined soya-bean oil[1] | 40.00 g |
| Alanine | 8.24 g |
| Arginine | 5.58 g |
| Aspartic acid | 1.65 g |
| Glutamic acid | 2.84 g |
| Glycine | 3.95 g |
| Histidine | 3.40 g |
| Isoleucine | 2.84 g |
| Leucine | 3.95 g |
| Lysine (equivalent to Lysine acetate) | 4.48 g (6.32 g ) |
| Methionine | 2.84 g |
| Phenylalanine | 3.95 g |
| Proline | 3.40 g |
| Serine | 2.25 g |
| Threonine | 2.84 g |
| Tryptophan | 0.95 g |
| Tyrosine | 0.15 g |
| Valine | 3.64 g |
| Sodium acetate, trihydrate | 1.50 g |
| Sodium glycerophosphate, hydrated | 3.67 g |
| Potassium chloride | 2.24 g |
| Magnesium chloride, hexahydrate | 0.81 g |
| Calcium chloride, dihydrate | 0.52 g |
| Glucose anhydrous (equivalent to Glucose monohydrate) | 110.00 g (121.00 g ) |

[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%.

For a full list of excipients, see the list of excipients session. .

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

| | **(1000 ml)** |
|---|---|
| Lipids | 40 g |
| Amino acids | 56.9 g |
| Nitrogen | 9.0 g |
| Glucose | 110.0 g |
| Energy:<br>Total calories approx.<br>Non-protein calories approx.<br>Glucose calories<br>Lipid calories approx.[2]<br><br>Non-protein calories / nitrogen ratio<br>Glucose / lipid calories ratio<br>Lipid / total calories | <br>1 070 kcal<br>840 kcal<br>440 kcal<br>400 kcal<br><br>93 kcal/g<br>52/48<br>37% |
| Electrolytes:<br>Sodium<br>Potassium<br>Magnesium<br>Calcium<br>Phosphate [3]<br>Acetate<br>Chloride | <br>35.0 mmol<br>30.0 mmol<br>4.0 mmol<br>3.5 mmol<br>15.0 mmol<br>54 mmol<br>45 mmol |
| pH approx. | 6.4 |
| Osmolarity approx. | 1 310 mosm/l |

[2] Includes calories from purified egg phosphatides
[3] Includes phosphate provided by the lipid emulsion

**PHARMACEUTICAL FORM**

Emulsion for infusion.

Appearance before reconstitution:
- The amino acids and glucose solutions are clear, colourless or slightly yellow,
- The lipid emulsion is homogenous with a milky appearance.

After reconstitution/mixing of the contents of the 3 compartments, OLIMEL N9E is a milk-like homogeneous liquid.

OLIMEL N9E is a hypertonic emulsion. The osmolarity and energy contents of the formulations are as follows :

| | |
|---|---|
| Osmolarity approx. (mOsm/L) | 1310 |
| Energy content approx. (kcal/L) | 1070 |

## CLINICAL PARTICULARS

### Therapeutic indications

OLIMEL N9E is indicated only for central parenteral nutrition for critically ill adults patients when oral or enteral nutrition is impossible, insufficient or contraindicated.
There is no safety data available for the use of Olimel N9E longer than 5 days.

### Posology and method of administration

Posology

*In adults*
The dosage depends on energy expenditure, the patient's clinical status and ability to metabolise constituents of OLIMEL, as well as additional energy or proteins given orally/enterally. Thus, the bag size should be then chosen with regard to the patient's body weight.

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 OLIMEL, the maximal daily dose is defined by fluid intake, 35 ml/kg corresponding to 2.0 g/kg of amino acids, 3.9 g/kg of glucose, 1.4 g/kg of lipids, 1.2 mmol/kg of sodium and 1.1 mmol/kg of potassium. For a 70 kg patient, this would be equivalent to 2 456 ml OLIMEL per day, resulting in an intake of 140 g of amino acids, 270 g of glucose and 98 g of lipids (i.e. 2 063 non-protein kcal and 2628 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 OLIMEL, the maximal infusion rate is 1.8 ml/kg/hour, corresponding to 0.10 g/kg/hour for amino acids, 0.19 g/kg/hour for glucose and 0.07 g/kg/hour for lipids.

*In Children*

There's no clinical studies in children

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.

For instructions for preparation and handling of the emulsion for infusion see section Special precautions for disposal and other handling .

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

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

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.

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

After opening the bag the content must be used immediately. It must never be stored for a subsequent infusion. Do not reconnect any partially used bag.

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

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

**Contraindications**

The use of OLIMEL is contra-indicated in the following situations:
- Hypersensitivity to egg, soybean, or peanut proteins, to any of the active substances or excipients
- Severe hyperlipidaemia or severe disorders of lipid metabolism characterised by hypertriglyceridemia,
- Severe hyperglycaemia,
- Pathologically-elevated plasma concentration of sodium, potassium, magnesium, calcium and/or phosphorus.

**Special warnings and precautions for use**

An excessively fast administration of total parenteral nutrition (TPN) solutions may result in severe or fatal consequences.

The infusion must be stopped immediately if any abnormal signs or symptoms of an allergic reaction (such as sweating, fever, shivering, headache, skin rashes or dyspnoea) develop. This medicinal product contains soya oil, which may rarely cause hypersensitivity reactions. Cross-allergic reactions between soybean and peanut have been observed.

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).
Monitor water and electrolyte balance, serum osmolarity, serum triglycerides, acid/base balance, blood glucose, liver and kidney function tests, coagulation and blood count, including platelets, throughout treatment.

Excess addition of calcium and phosphorus may result in the formation of calcium phosphate precipitates that could lead to vascular occlusion.

Severe water and electrolyte equilibration disorders, severe fluid overload states, and severe metabolic disorders must be corrected before starting the infusion.

Specific clinical monitoring is required when an intravenous infusion is started.

Vascular-access infection and sepsis are complications that may occur in patients receiving parenteral nutrition, particularly in case of poor maintenance of catheters, immunosuppressive effects of illness or drugs. Careful monitoring of signs, symptoms, and laboratory test results for fever/chills, leukocytosis, technical complications with the access device, and hyperglycemia can help recognize early infections. Patients who require parenteral nutrition are often predisposed to infectious complications due to malnutrition and/or their underlying disease state. The occurrence of septic complications can be decreased with heightened emphasis on aseptic techniques in catheter placement and maintenance, as well as aseptic techniques in the preparation of the nutritional formula.

Pulmonary vascular precipitates causing pulmonary vascular emboli and pulmonary distress have been reported in patients receiving parenteral nutrition. In some case, fatal outcomes have been occurred. Excessive addition of calcium and phosphate increases the risk of the formation of calcium phosphate precipitates. Precipitates have been reported even in the absence of phosphate salt in the solution. Suspected precipitate formation in the blood stream have also reported.
In addition to inspection of the solution, the infusion set and catheter should also periodically be checked for precipitates.
If signs of pulmonary distress occur, the infusion should be stopped and medical evaluation initiated.

Elevated liver enzymes and cholestasis have been reported with similar products. Monitoring of serum ammonia should be considered if hepatic insufficiency is suspected.

Metabolic complications may occur if the nutrient intake is not adapted to the patient's requirements, or the metabolic capacity of any given dietary component is not accurately assessed. Adverse metabolic effects may arise from administration of inadequate or excessive nutrients or from inappropriate composition of an admixture for a particular patient's needs.

Administration of amino acid solutions may precipitate acute folate deficiency, folic acid is therefore recommended to be given daily.

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 OLIMEL, if applicable) and the stage/extent 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 first 24 hours, then once daily.

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

Cardiovascular
Use with caution in patients with pulmonary oedema or heart failure. Fluid status should be closely monitored.

Hepatic Insufficiency
Use with caution in patients with hepatic insufficiency because of the risk of developing or worsening neurological disorders associated with hyperammonaemia. Regular clinical and laboratory tests are required, particularly liver function parameters, blood glucose, electrolytes and triglycerides.

Renal Insufficiency
Use with caution in patients with renal insufficiency, particularly if hyperkalaemia is present, because of the risk of developing or worsening metabolic acidosis and hyperazotemia if extra-renal waste removal is not being performed. Fluid, triglycerides and electrolyte status should be closely monitored in these patients.

Hematologic
Use with caution in patients with coagulation disorders and anaemia. Blood count and coagulation parameters should be closely monitored.

Endocrine and Metabolism
Metabolic complications may occur if the nutrient intake is not adapted to the patient's requirements, or the metabolic capacity of any given dietary component is not accurately assessed. Adverse metabolic effects may arise from administration of inadequate or excessive nutrients or from inappropriate composition of an admixture for a particular patient's needs.
Serum triglyceride concentrations and the ability of the body to metabolise lipids must be checked regularly. If a lipid metabolism abnormally is suspected, monitoring of serum triglycerides is recommended as clinical necessary.

Use with caution, regular clinical and laboratory test are required particularly in patient with :

- amino acid metabolism disorders (see CONTRAINDICATIONS)
- hepatic insufficiency because of the risk of developing or worsening neurological disorder associated with hyperammonaemia
- renal insufficiency, particularly if hyperkalaemia is present; risk of developing or worsening metabolic acidosis and hyperazotaemia if extra-renal waste removal is not being performed
- metabolic acidosis (administration of carbohydrate is not recommended in the presence of lactic acidosis)
- diabetes mellitus : monitoring of glucose concentration, glucosuria, ketonuria, and where applicable, adjustment of insulin dosages
- coagulation disorders
- anaemia
- hyperlipidaemia (because of the presence of lipids in the emulsion for infusion)

The blood count and coagulation factors must be monitored more carefully during long term administration (several weeks)

Serum triglycerides concentrations and the ability of the body to remove lipids must be checked regularly.

Serum triglycerides concentrations must not exceed 3 mmol/l during the infusion.

If a lipid metabolism abnormality is suspected, it is recommended to measure daily the serum triglycerides after a period of 5 to 6 hours without administering lipids. In adults, the serum must be clear in less than 6 hours after stopping the infusion containing the lipid emulsion. The next infusion must only be administered when the serum triglycerides concentrations have returned to pre-existing values.

Fat overload syndrome has been reported with similar products
This may caused by inappropriate administration (e.g. overdose and/or infusion rate higher than recommended, see OVERDOSAGE); however the signs and symptoms of this syndrome may also occur when the product is administered according to the instruction. The reduced or limited ability to metabolise the lipids contained in OLIMEL N9E accompanied by prolonged plasma clearance may result in fat overload syndrome. This syndrome is associated with a sudden deterioration in the patient's clinical condition and is characterised by finding such as fever, anemia, leucopenia, thrombocytopenia, coagulation disorders, hyperlipidaemia, liver fatty infiltration (hepatomegaly), deteriorating liver functions, and central nervous system manifestations (e.g. coma). The syndrome is usually reversible when the infusion of the lipid emulsion is stopped.
In the event of hyperglycemia, the infusion rate of OLIMEL must be adjusted and/or insulin administered.

**DO NOT ADMINISTER THROUGH A PERIPHERAL VEIN**.

When making additions, the final osmolarity of the mixture must be measured before administration. The mixture obtained must be administered through a central or peripheral venous line depending on its final osmolarity.
If the final mixture, which is administered, is hypertonic, it may cause irritation of the vein when administered into a peripheral vein.
OLIMEL N9Emust be only be administered through a central vein

Although there is a natural content of trace elements and vitamins in the product, the levels are insufficient to meet body requirements, and these should be added to prevent deficiencies from developing. See instructions for making additions to this product.

Caution should be exercised in administering OLIMEL to patients with increased osmolarity, adrenal insufficiency, heart failure or pulmonary dysfunction.

In malnourished patients, initiation of parenteral nutrition can precipitate fluid shifts resulting in pulmonary oedema and congestive heart failure as well as a decrease in the serum concentration of potassium, phosphorus, magnesium and water-soluble vitamins. These changes can occur within 24 to 48 hours, therefore careful and slow initiation of parenteral nutrition is recommended together with close monitoring and appropriate adjustments of fluid, electrolytes, trace elements and vitamins.

Refeeding severely undernourished patients may result in the refeeding syndrome that is characterised by the shift of potassium, phosphorus and magnesium intracellularly as the patient become anabolic. Thiamine deficiency and fluid retention may also develop. Careful monitor and slowly increasing nutrient intakes while avoiding overfeeding can prevent these complications. This syndrome has been reported with similar products.

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

**Interaction with other medicinal products and other forms of interaction**

No interaction studies have been performed.

OLIMEL must not be administered simultaneously with blood through the same infusion tubing because of the possibility of pseudoagglutination.

The lipids contained in this emulsion may interfere with the results of certain laboratory tests (for example, bilirubin, lactate dehydrogenase, oxygen saturation, blood haemoglobin) if the blood sample is taken before the lipids are eliminated (these are generally eliminated after a period of 5 to 6 hours without receiving lipids).

Do not add other medicinal products or substances to one of the three components of the bag or to the reconstituted emulsion without firstly confirming their compatibility and the stability of the resulting preparation (in particular stability of the lipid emulsion or formation of precipitates).

Ceftriaxone must not be administered simultaneously with intravenous calcium-containing solutions, including OLIMEL, through the same infusion line (e.g., Yconnector) because of the risk of precipitation of ceftriaxone-calcium salt.

If the same infusion line is used for sequential administration, the line must be thoroughly flushed with a compatible fluid (e.g. physiological salt-solution) to avoid precipitation.

OLIMEL contains vitamin K, naturally present in lipid emulsions. The amount of vitamin K in recommended doses of OLIMEL are not expected to influence effects of coumarin derivatives.

Due to the potassium content of OLIMEL, special care should be taken in patients treated with potassium-sparing diuretics (e.g., amiloride, spironolactone, triamterene), angiotensin converting enzyme (ACE) inhibitors, angiotensin II receptor antagonists, or the immunosuppressants tacrolimus or cyclosporine in view of the risk of hyperkalemia.

**Fertility, Pregnancy and lactation**

Effect on Fertility
No studies have been conducted to assess the effect of OLIMEL N9E on fertility.

Use in pregnancy (Category – exempt)
There are no adequatel data from the use of OLIMEL in pregnant women.
Physician should carefully consider the potential risk and benefits for each specific patient before prescribing OLIMEL N9E.

**Use in Lactation**
There are no adequate data on the use of OLIMEL N9E in lactating women. Following intravenous infusion, most of the active ingredients contained in OLIMEL N9E are expected to be excreted in human milk and the safety of breastfeeding infant has not been established. Physicians should carefully consider the potential risk and benefits for each specific patient before prescribing OLIMEL N9E.

**Effects on ability to drive and use machines**
No studies on the effects on the ability to drive and use machines have been performed.

**Undesirable effects**

Potential undesirable effects may occur as a result of inappropriate use (for example: overdose, excessively fast infusion rate)

At the beginning of the infusion, any of the following abnormal signs (sweating, fever, shivering, headache, skin rashes, dyspnoea) should be cause for immediate discontinuation of the infusion:

The following adverse drug reactions (ADRs) were reported with OLIMEL 9 g/l nitrogen 1070 kcal/l in a randomized, double-blind, active-controlled, efficacy and safety study. Twenty-eight patients with various medical conditions (i.e., postsurgical fasting, severe malnutrition, enteral intake insufficient or forbidden) were included and treated; patients in the OLIMEL group received drug product up to 40 ml/kg/d over 5 days.

| System Organ Class | MedDRA Preferred Term | Frequency[a] |
|---|---|---|
| Cardiac Disorders | Tachycardia | Common |
| Metabolism and Nutrition Disorders | Anorexia | Common |
| | Hypertriglyceridemia | Common |
| Gastrointestinal Disorders | Abdominal pain | Common |
| | Diarrhoea | Common |
| | Nausea | Common |
| Vascular Disorders | Hypertension | Common |
| General disorders and administration site conditions | Extravasation which may result at infusion site level in: pain, irritation, swelling/oedema, erythema/warmth, skin necrosis, blisters | Not known[b] |

a: Frequency is defined as very common (≥ 1/10); common (≥ 1/100 to < 1/10); uncommon (≥ 1/1000 to < 1/100); rare (≥ 1/10,000 to < 1/1000); very rare (< 1/10,000); or not known (cannot be estimated from the available data).
b: ADRs reported during post-marketing experience with OLIMEL.

The following class-like-adverse drug reactions (ADRs) have been described in other sources in relation to similar parenteral nutrition products; the frequency of these events is not known.

- Blood and Lymphatic System Disorders: Thrombocytopenia
- Hepatobiliary Disorders: Cholestasis, Hepatomegaly, Jaundice
- Immune System Disorders: Hypersensitivity
- Investigations: Blood alkaline phosphatase increased, Transaminases increased, Blood bilirubin increased, Elevated liver enzymes
- Renal and Urinary Disorders: Azotemia

**Overdose**

In the event of inappropriate administration (overdose and/or infusion rate higher than recommended), signs of hypervolaemia and acidosis may occur.

An excessively fast infusion or administration of a too large volume may cause nausea, vomiting, shivering and electrolyte disturbances. In such situations the infusion must be stopped immediately.

Hyperglycaemia, glucosuria, and a hyperosmolar syndrome may develop if glucose infusion rate exceeds clearance.

A reduced ability to remove lipids may result in a "fat overload syndrome", the effects of which are usually reversible after the lipid infusion is stopped.

In some serious cases, haemodialysis, haemofiltration or haemodiafiltration may be necessary.

**PHARMACOLOGICAL PROPERTIES**

**Pharmacodynamic properties**

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

OLIMEL's content in nitrogen (L series amino acids) and energy (glucose and triglycerides) enables maintaining an adequate nitrogen/energy balance.

This formulation also contains electrolytes.

The lipid emulsion included in OLIMEL is an association of refined olive oil and refined soybean oil (ratio 80/20), with the following approximate distribution of fatty acids:
- 15% saturated fatty acids (SFA)
- 65% monounsaturated fatty acids (MUFA)
- 20% polyunsaturated essential fatty acids (PUFA)

The phospholipid/triglyceride ratio is 0.06.

Olive oil contains significant amount of alpha-tocopherol which, combined with a moderate PUFA intake, contributes to improve the vitamin E status and to reduce the lipid peroxidation.

The amino acids solution contains 17 L series amino acids (including 8 essential amino acids), which are indispensable for protein synthesis.

Amino acids also represent an energy source. Their oxidation results in excretion of nitrogen in the form of urea.

The amino acids profile is as follows:
- Essential amino acids/total amino acids: 44.8%
- Essential amino acids (g)/total nitrogen (g): 2.8%
- Branched-chain amino acids/total amino acids: 18.3%

The carbohydrate source is glucose.

**Pharmacokinetic properties**

The ingredients of OLIMEL (amino acids, electrolytes, glucose and lipids) are distributed, metabolised and removed in the same way as if they had been administered individually.

**Preclinical safety data**

No preclinical studies with OLIMEL have been performed.

Preclinical toxicity studies performed using the lipid emulsion contained in OLIMEL have identified the changes, which are conventionally found with a high intake of a lipid emulsion: fatty liver, thrombocytopaenia and elevated cholesterol.

Preclinical studies performed using the solutions of amino acids and glucose contained in OLIMEL of different qualitative compositions and concentrations have not, however, revealed any specific toxicity.

**PHARMACEUTICAL PARTICULARS**

**List of excipients**

Lipid emulsion compartment:
Purified egg phosphatide, Glycerol, Sodium oleate, Sodium hydroxide (for pH adjustment), Water for injections.

Compartment of amino-acid solution with electrolytes:
Glacial acetic acid (for pH adjustment), Water for injections.

Compartment of glucose solution with calcium:
Hydrochloric acid (for pH adjustment), Water for injections.

**Incompatibilities**

Incompatibilities may be produced for example by excessive acidity (low pH) or inappropriate content of divalent cations ($Ca^{2+}$ and $Mg^{2+}$), which may de-stabilize 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.

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

Ceftriaxone must not be administered simultaneously with intravenous calcium containing solutions, including OLIMEL, through the same infusion line (e.g., via Y-connector) because of the risk of precipitation of ceftriaxone-calcium salt.

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

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

**Shelf life**

2 years if the overwrap is not damaged.

After reconstitution

It is recommended that the product be used immediately after the non-permanent seals between the 3 compartments have been opened. 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 25°C.

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. If not used immediately, storage times and conditions, after mixing and 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.

**Special precautions for storage**

Do not freeze.
Store in the overpouch.
For storage conditions of the reconstituted medicinal product.

**Nature and contents of container**

The three-compartment bag is a multi-layer plastic bag. The inner (contact) layer of the bag material is made of a blend of polyolefinic copolymers and is compatible with amino acid solutions, glucose solutions and lipid emulsions. Other layers are made of poly-ethylene vinyl acetate (EVA), and of copolyester.

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 and may include an oxygen indicator.

Pack sizes:

1 000 ml bag: 1 carton with 6 bags

**Special precautions for disposal and other handling**

Before opening the overpouch and if present, check the colour of the oxygen indicator. Compare it to the reference colour printed next to the OK symbol and depicted in the printed area of the indicator label. Do not use the product if the colour of the oxygen indicator does not correspond to the reference colour printed next to OK symbol.

To open

Remove the protective overpouch.

Discard the oxygen absorber / oxygen indicator sachet.

Confirm the integrity of the bag and of the non-permanent seals. Use only if the bag is not damaged, if the non-permanent seals are intact (i.e. no mixture of the contents of the three compartments), if the amino acids solution and the glucose solution are clear, colourless or slightly yellow, 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 non-permanent seals.

Manually roll the bag onto itself, starting at the top of the bag (hanger end). The non-permanent seals will disappear from the side near the inlets. Continue to roll 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 addition (including vitamins) may be made into the reconstituted mixture (after the non-permanent seals have been opened and after the contents of the three compartments have been mixed).

Vitamins may also be added into the glucose compartment before the mixture is reconstituted (before opening the non-permanent 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.

OLIMEL may be supplemented with electrolytes according to the tables 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[(5)]) mmol | 5.0 (3.5[(5)])mmol |
| Inorganic Phosphate | 0 mmol | 3.0 mmol | 3.0 mmol |
| Organic Phosphate | 15 mmol [(4)] | 10 mmol | 25 mmol [(4)] |

[4] Including phosphate provided by the lipid emulsion
[5] Value corresponding to the addition of inorganic phosphate

*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.

When making additions, the final osmolarity of the mixture must be measured before administration via a peripheral vein.

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.

**Presentation**
1 flexy bag @ 1000 mL
Reg. No. DKI1710700349A1

Store at temperature not exceeding 30ºC

**Manufactured by :**
BAXTER S.A.
Boulevard Rene Branquart, 80
7860 Lessines
Belgium

**IMPORTED AND DISTRIBUTED BY :**
PT. Kalbe Farma Tbk.
Bekasi – Indonesia

On Medical Prescription only
Harus Dengan Resep Dokter

**DATE OF REVISION OF THE TEXT**
October 2017

**Patient Information Leaflet**

OLIMEL N9E, emulsi untuk infus
(Glukosa : Asam amino : Lemak = 27,5% : 14,2% : 20%)

Baca seluruh *leaflet* ini dengan teliti sebelum Anda mendapatkan terapi Olimel karena informasinya penting untuk Anda ketahui.
- Simpan *leaflet*. Anda mungkin membutuhkannya untuk membaca kembali.
- Jika Anda memiliki pertanyaan lebih lanjut, tanyakan pada dokter atau perawat Anda.
- Jika Anda mengalami efek samping, konsultasikan dengan dokter atau perawat Anda. Hal ini termasuk efek samping yang tidak tertulis di *leaflet* ini. Lihat ruang 4.

Apa saja yang ada di dalam *leaflet* ini:


## 1. Apakah OLIMEL itu dan digunakan untuk apa?

OLIMEL merupakan emulsi untuk infus, dalam bentuk kantong dengan 3 ruang.
Satu ruang mengandung larutan glukosa dengan kalsium, ruang kedua mengandung emulsi lemak dan ruang ketiga mengandung larutan asam amino dengan elektrolit lainnya.
OLIMEL digunakan untuk memenuhi nutrisi melalui selang kedalam pembuluh darah ketika pemberian makan melalui mulut tidak dapat dilakukan.
OLIMEL hanya digunakan di bawah pengawasan tenaga medis.

## 2. Apa yang harus Anda ketahui sebelum diberikan infus OLIMEL?

OLIMEL tidak dapat digunakan apabila Anda:
- Hipersensitif (alergi) dengan telur, protein kedelai atau kacang atau bahan lainnya.
- Mengalami masalah dalam penggunaan asam amino tertentu.
- Mempunyai kadar lemak dalam darah yang tinggi.
- Mengalami hiperglikemia (kelebihan kadar gula darah).
- Mempunyai jumlah elektrolit dalam darah yang abnormal (natrium, kalium, magnesium, kalsium, dan/atau fosfor).

Dokter memberikan OLIMEL dengan mempertimbangkan berbagai faktor seperti umur, berat badan, kondisi medis, dan hasil tes yang sudah dilakukan.

### Peringatan dan perhatian

Bicarakan dengan dokter atau perawat Anda sebelum Anda diberikan OLIMEL.

Infus harus segera dihentikan jika terdapat tanda atau gejala abnormal dari berkembangnya reaksi alergi (seperti berkeringat, demam, menggigil, sakit kepala, kulit kemerahan, atau kesulitan bernafas). Produk ini mengandung minyak kedelai dan *purified egg phosphatide*. Protein kedelai dan telur mungkin dapat menyebabkan reaksi hipersensitivitas.

Jika Anda mengalami sesak napas, beritahukan dokter atau perawat Anda. Sesak napas dapat menjadi pertanda terbentuknya endapan kecil, yang menyumbat pembuluh darah di paru. Antibiotik *Ceftriaxone* tidak dapat dicampur atau diberikan secara bersamaan dengan OLIMEL secara tetesan infus kedalam pembuluh darah Anda, sekalipun melalui selang infus atau tempat infus yang berbeda.

OLIMEL dan *Ceftriaxone* hanya dapat diberikan secara berurutan satu per satu dengan menggunakan selang infus di tempat yang berbeda atau jika selang infus diganti atau dibilas dengan larutan garam fisiologis untuk menghindari pembentukan endapan (bentuk partikel dari *Ceftriaxone* dan garam kalsium).

Pasien yang mendapatkan nutrisi parenteral (pemberian nutrisi melalui selang kedalam pembuluh darah Anda) memiliki risiko untuk terjadi infeksi. Penggunaan tehnik aseptik (”bebas kuman”) ketika memasang dan merawat kateter serta ketika pemberian nutrisi dapat menurunkan risiko infeksi.

Jika Anda memiliki status gizi yang kurang sehingga membutuhkan makanan melalui pembuluh darah, dokter biasanya akan memulai pemberian nutrisi parenteral secara perlahan sambil memantau perubahan kadar air, vitamin, elektrolit dan mineral di dalam tubuh Anda.

Keseimbangan air dan garam di dalam tubuh Anda dan gangguan metabolik akan dikoreksi terlebih dahulu sebelum memulai pemberian OLIMEL. Tambahan zat nutrisi, seperti vitamin, elektrolit, dan mineral dapat diberikan jika merasa diperlukan.

Anda harus menginformasikan dokter Anda apabila:
- Mengidap penyakit ginjal berat. Anda juga harus menginformasikan ke dokter Anda jika Anda sedang menjalani cuci darah.
- Atau jika Anda menjalani terapi pembersihan darah lainnya.
- Penyakit hati berat.
- Penyakit pembekuan darah.
- Kelenjar adrenal tidak dapat bekerja dengan baik (insufisiensi adrenal). Kelenjar adrenal merupakan kelenjar dalam bentuk segitiga yang terdapat di ruang atas dari ginjal Anda.
- Gagal jantung.
- Penyakit paru.
- Kelebihan air di dalam tubuh Anda (hiperhidrasi).
- Kekurangan air di dalam tubuh Anda (dehidrasi).
- Gula darah tinggi yang tidak diterapi (diabetes melitus).
- Memiliki riwayat serangan jantung atau syok sampai dengan gagal jantung mendadak.
- Asidosis metabolik berat (ketika darah menjadi sangat asam).
- Infeksi luas (septikemia).
- Koma.

Untuk mengetahui efektivitas dan keamanan, dokter Anda akan melakukan pemeriksaan klinis dan laboratorium selama pemberian OLIMEL.
Jika selama pemberian infus Anda merasa nyeri, terbakar atau bengkak di tempat infus, atau bocor dari infusan, beritahu dokter atau perawat Anda. Pemberian akan segera dihentikan dan mulai diberikan kembali di pembuluh darah yang berbeda.

Jika gula darah Anda menjadi sangat tinggi, dokter Anda akan menyesuaikan kecepatan pemberian OLIMEL atau memberi Anda obat-obatan untuk mengendalikan gula darah (insulin).

OLIMEL hanya dapat diberikan melalui selang infus (kateter) kedalam pembuluh darah besar di rongga dada Anda (vena sentral).

**Obat lain dan OLIMEL**

Beritahukan dokter Anda jika Anda mengonsumsi atau menggunakan, baru saja mengonsumsi atau menggunakan atau mungkin mengonsumsi atau menggunakan obat-obatan lainnya.

Jika Anda mengonsumsi produk lain, dengan atau tanpa resep, Anda wajib memberitahukan ke dokter Anda agar dilakukan kesesuaian lebih lanjut.

OLIMEL tidak boleh diberikan secara bersamaan dengan darah melalui selang infus yang sama.

Minyak zaitun dan kedelai yang terdapat di OLIMEL mengandung vitamin K. Hal ini biasanya tidak mempengaruhi kerja obat pengencer darah (antikoagulan) seperti *cumarin*. Namun, jika Anda mengonsumsi obat antikoagulan wajib memberitahu dokter Anda.

Lemak yang terkandung di dalam OLIMEL dapat mempengaruhi hasil dari pemeriksaan laboratorium ketika sampel darah diambil sebelum lemak dibersihkan dari aliran darah (sebaiknya pemberian OLIMEL dihentikan 5-6 jam sebelum pengambilan sampel darah).

OLIMEL mengandung kalium. Perhatian khusus harus diberikan pada pasien yang mendapatkan terapi diuretik, *ACE-inhibitor*, antagonis reseptor angiotensin II (ketiganya adalah golongan obat untuk tekanan darah tinggi), atau imunosupresan (obat untuk menekan daya tahan tubuh).

Obat-obatan jenis tersebut dapat meningkatkan kadar kalium dalam darah.

**Kehamilan, menyusui dan fertilitas**
Jika Anda sedang hamil atau menyusui, berpikir untuk hamil atau berencana mempunyai anak, tanyakan pendapat dokter Anda sebelum mendapatkan OLIMEL.
OLIMEL dapat diberikan selama hamil atau menyusui, jika memang dibutuhkan.

## 3. Bagaimana OLIMEL digunakan?

**Dosis**
OLIMEL hanya diberikan untuk usia dewasa.
OLIMEL merupakan emulsi untuk infus, diberikan melalui selang infus (kateter) kedalam pembuluh darah di rongga dada Anda.
OLIMEL harus disimpan pada suhu ruangan sebelum digunakan.
OLIMEL hanya digunakan sekali pakai.
Infus 1 kantong biasanya diberikan antara 12-24 jam.

Dokter Anda akan menentukan kecepatan sesuai dengan kebutuhan dan kondisi klinis Anda. Peresepan dapat dilanjutkan selama dibutuhkan, tergantung kondisi klinis Anda.

**Jika Anda mendapatkan OLIMEL lebih banyak dari yang seharusnya.**

Jika dosis diberikan terlalu tinggi atau infus yang terlalu cepat, kandungan asam amino mungkin dapat membuat darah Anda menjadi lebih asam, dan volume darah menjadi berlebih. Kadar glukosa dalam darah dan urin Anda dapat meningkat, demikian pula kekentalan darah. Kandungan lemak dapat meningkatkan kadar trigliserida dalam darah Anda. Menerima volume OLIMEL dalam jumlah besar dapat menyebabkan mual, muntah, menggigil dan gangguan elektrolit.
Pada situasi seperti ini, infus OLIMEL harus segera dihentikan.
Pada beberapa kasus yang berat, dokter Anda mungkin harus memberikan dialisis sementara untuk membantu mengeliminasi produk yang berlebihan melalui ginjal.
Untuk mencegah kejadian ini terjadi, dokter Anda akan secara teratur memonitor kondisi Anda dan memeriksa parameter darah Anda.
Jika Anda mempunyai pertanyaan lebih lanjut terkait produk ini, tanyakan pada dokter Anda.

## 4. Kemungkinan efek samping

Seperti semua obat-obatan, obat ini dapat menyebabkan efek samping, meskipun tidak semua orang dapat mengalaminya.
Jika Anda melihat ada perubahan seperti yang Anda rasakan selama atau setelah terapi, segera beritahu dokter atau perawat Anda.
Pemeriksaan yang dilakukan oleh dokter Anda selama mengonsumsi obat harus meminimalkan risiko efek samping.
Jika terdapat tanda atau gejala abnormal yang berkembang dari reaksi alergi, seperti berkeringat, demam, menggigil, sakit kepala, kemerahan, atau kesulitan bernapas, OLIMEL harus segera dihentikan.

Berikut efek samping yang telah dilaporkan dari penggunaan OLIMEL:

Frekuensi-Sering: dapat mengenai 1 dari 10 orang
- Detak jantung yang cepat (takikardi)
- Hilangnya napsu makan (anoreksia)
- Meningkatnya kadar lemak di dalam darah (hipertrigliseridemia)
- Nyeri rongga perut
- Diare
- Mual
- Meningkatnya tekanan darah (hipertensi)

Frekuensi-Tidak diketahui: frekuensi tidak dapat diperkirakan dari data yang ada
- Kebocoran OLIMEL ke jaringan sekitar (ekstravasasi) yang dapat menyebabkan rasa nyeri, iritasi, pembengkakan/edema, kemerahan (eritema)/rasa panas, kematian jaringan sel (nekrosis kulit) atau melepuh di tempat infus.

Berikut efek samping yang telah dilaporkan dari nutrisi parenteral yang sejenis:

Frekuensi-Sangat jarang: dapat mengenai 1 dari 10.000 orang
- Penurunan kemampuan untuk mengeluarkan lemak (*fat overload syndrome*). Berikut tanda *fat overload syndrome* yang biasanya bersifat reversibel jika infus lemak dihentikan:
  - Demam

- Penurunan sel darah merah yang dapat membuat kulit pucat dan menyebabkan kelemahan atau sesak napas (anemia)
- Rendahnya jumlah sel darah putih, yang dapat meningkatkan risiko infeksi (leukopenia)
- Rendahnya jumlah trombosit yang bisa meningkatkan risiko lebam dan/atau perdarahan (trombositopenia)
- Gangguan pembekuan darah yang berdampak pada kemampuan darah untuk pembekuan
- Tingginya kadar lemak darah (hiperlipidemia)
- Infiltrasi perlemakan hati (hepatomegali)
- Fungsi hati yang memburuk
- Manifestasi sistem saraf pusat (contoh. koma)

Frekuensi-Tidak diketahui: frekuensi tidak bisa diperkirakan dari data yang ada
- Reaksi alergi
- Hasil tes darah abnormal untuk fungsi hati
- Gangguan eliminasi asam empedu (kolestasis)
- Pembesaran hati (hepatomegali)
- Kuning (*jaundice*)
- Penurunan jumlah keping darah (trombositopenia)
- Peningkatan kadar nitrogen dalam darah (azotemia)
- Pembentukan endapan kecil dapat memicu penyumbatan pembuluh darah di paru yang menyebabkan kesulitan bernapas.

**Efek samping yang dilaporkan**
Jika Anda mengalami efek samping, bicarakan dengan dokter atau perawat Anda, termasuk efek samping yang tidak tertera di dalam *leaflet*. Anda juga dapat melaporkan efek samping secara langsung (lihat lengkapnya di bawah). Dengan melaporkan efek samping, Anda telah membantu memberikan informasi lebih lanjut keamanan obat ini.

## 5. Bagaimana penyimpanan OLIMEL?

Jauhkan obat ini dari penglihatan dan jangkauan anak.
Jangan gunakan obat ini setelah tanggal kadaluarsa yang tertera di kantong dan kemasan luar (bulan/tahun). Tanggal kadaluarsa mengikuti hari terakhir di bulan yang tertera.
Jangan dibekukan.
Simpan di dalam kemasan luarnya.
Jangan membuang OLIMEL melalui air limbah atau sampah rumah tangga. Tanyakan ke ruang farmasi, bagaimana membuang OLIMEL yang sudah tidak digunakan. Langkah ini akan membantu melindungi lingkungan.

## 6. Kandungan dan informasi lainnya.

OLIMEL mengandung L-asam amino14,2% (setara dengan 14,2 g/100 mL) (alanin, arginin, glisin, histidin, isoleusin, leusin, lisin, (sebagai lisin asetat), metionin, fenilalanin, prolin, serin, treonin, triptofan, tirosin, valin, asam aspartat, asam glutamat) dengan elektrolit (natrium, kalium, magnesium, fosfat, asetat, klorida), emulsi lemak 20% (setara dengan 20 g/100 mL) (*refined olive oil* dan *refined soybean oil*), dan larutan glukosa 27,5% (setara dengan 27,5 g/100 mL) (sebagai glukosa monohidrat) dengan kalsium.

Kandungan lainnya:

| Ruang emulsi lemak | Ruang larutan asam amino | Ruang larutan glukosa |
|---|---|---|
| *Purified egg phosphatide,* gliserol, natrium oleat, natrium hidroksida (penyesuaian pH), air untuk injeksi | Asam asetat glasial (penyesuaian pH), air untuk injeksi | Asam hidroklorik (penyesuaian pH), air untuk injeksi |

OLIMEL merupakan emulsi untuk infus yang dikemas dengan kantong 3 ruang. Satu ruang mengandung emulsi lemak, ruang lainnya mengandung larutan asam amino dengan elektrolit dan ruang ketiga mengandung larutan glukosa dengan kalsium. Ruang ini dipisahkan oleh sekat non-permanen. Sebelum pemberian, isi ruang perlu dicampur dengan dengan menggulung kantong, dimulai dari ruang atas sampai *peal sekat* terbuka.

**Tampilan sebelum dicampur:**
- Larutan asam amino dan glukosa jernih, tidak berwarna, atau sedikit kekuningan.
- Emulsi lemak homogen dengan tampilan seperti susu.

**Tampilan setelah dicampur: emulsi homogen seperti susu**
Kantong 3 ruang merupakan kantong plastik *multilayer*. Material lapisan dalam kantong didesain kompatibel terhadap penyusun dan pelarut zat tambahan.
Untuk mencegah kontak dengan oksigen yang terkandung dalam udara, kantong dikemas dengan penghambat oksigen di *overpouch* dengan *sachet* penyerap oksigen termasuk indikator oksigen (OXYDETECT).

**Ukuran kemasan**
Kantong 1000 mL

Reg. No. DKI1710700349A1

Simpan pada suhu di bawah 30$^{o}$C

Diproduksi oleh :
**BAXTER S.A.**
Boulevard Rene Branquart, 80
7860 Lessines
Belgium

Diimpor dan Didistribusikan oleh:
PT. Kalbe Farma Tbk.
Bekasi – Indonesia

On Medical Prescription only
Harus Dengan Resep Dokter

**Informasi berikut hanya ditujukan untuk medis atau profesional kesehatan:**

Olimel 9 g/L nitrogen 1070 Kkal/L dengan elektrolit, emulsi untuk infus

## KOMPOSISI KUALITATIF DAN KUANTITATIF

OLIMEL tersedia dalam bentuk kantong dengan 3 ruang. Tiap kantong mengandung larutan glukosa dengan kalsium, emulsi lemak dan larutan asam amino dengan elektrolit.

| | **Kandungan tiap kantong 1000 mL** |
|---|---|
| Larutan glukosa 27,5%<br>(setara dengan 27,5 g/100 mL) | 400 mL |
| Larutan asam amino 14,2%<br>(setara dengan 14,2 g/100 mL) | 400 mL |
| Emulsi lemak 20%<br>(setara dengan 20 g/100 mL) | 200 mL |

Komposisi emulsi yang dilarutkan setelah pencampuran kandungan 3 ruang:

| **Zat Aktif** | **1000 mL** |
|---|---|
| *Refined olive oil*+ *refined soybean oil*[1] | 40,00 g |
| Alanin | 8,24 g |
| Arginin | 5,58 g |
| Asam aspartate | 1,65 g |
| Asam glutamat | 2,84 g |
| Glisin | 3,95 g |
| Histidin | 3,40 g |
| Isoleusin | 2,84 g |
| Leusin | 3,95 g |
| Lisin<br>(setara dengan Lisin asetat) | 4,48 g<br>(6,32 g ) |
| Metionin | 2,84 g |
| Fenilalanin | 3,95 g |
| Prolin | 3,40 g |
| Serin | 2,25 g |
| Treonin | 2,84 g |
| Triptofan | 0,95 g |
| Tirosin | 0,15 g |
| Valin | 3,64 g |
| Natrium asetat, trihidrat | 1,50 g |
| Natrium gliserofosfat, terhidrasi | 3,67 g |
| Kalium klorida | 2,24 g |
| Magnesium klorida, heksahidrat | 0,81 g |
| Calcium klorida, dehidrat | 0,52 g |
| Glukosa anhidrous<br>(setara dengan Glukosa monohidrat) | 110,00 g<br>(121,00 g ) |

[1] Campuran dari *refined olive oil* (sekitar 80%) dan *refined soybean oil* (sekitar 20%) sesuai dengan rasio asam lemak/total asam lemak 20%.

Untuk daftar eksipien lengkap, lihat daftar ruang eksipien.

Asupan nutrisi dari masing-masing kantong yang sudah dilarutkan:

| | **1000 mL** |
|---|---|
| Lemak | 40 g |
| Asam amino | 56,9 g |
| Nitrogen | 9,0 g |
| Glukosa | 110,0 g |
| Energi: | |
| Total kalori sekitar. | 1 070 Kkal |
| Kalori non-protein sekitar. | 840 Kkal |
| Kalori glukosa | 440 Kkal |
| Kalori lemak sekitar.[(2)] | 400 Kkal |
| Non-protein calories / nitrogen ratio | 93 Kkal/g |
| Glucose / lipid calories ratio | 52/48 |
| Lipid / total calories | 37% |
| Elektrolit: | |
| Natrium | 35,0 mmol |
| Kalium | 30,0 mmol |
| Magnesium | 4,0 mmol |
| Kalsium | 3,5 mmol |
| Fosfat [(3)] | 15,0 mmol |
| Asetat | 54 mmol |
| Klorida | 45 mmol |
| pH sekitar. | 6,4 |
| Osmolaritas sekita. | 1310 mOsm/L |

[2] Termasuk kalori dari *purified egg phosphatides*
[3] Termasuk fosfat yang disediakan oleh emulsi lemak

**Posologi dan metode pemberian**

Posologi

Pada dewasa
Dosis tergantung kebutuhan energi, status klinis pasien dan kemampuan untuk memetabolisme kandungan OLIMEL, begitu juga penambahan energi atau protein yang diberikan secara oral/enteral. Dengan demikian, pemilihan ukuran kantong disesuaikan dengan berat badan pasien.

Rerata kebutuhan harian:
- Nitrogen 0,16-0,35 g/kgBB (asam amino 1-2 g/kgBB), tergantung status nutrisi pasien dan derajat katabolik stres,
- 20-40 Kkal/kgBB,
- Cairan 20-40 mL/kgBB, atau 1-1,5 mL/Kkal.

Untuk OLIMEL, dosis harian maksimum didefinisikan dengan asupan cairan, 35 mL/kgBB sesuai dengan asam amino 2,0 g/kgBB, glukosa 3,9 g/kgBB, natrium 1,2 mmol/kgBB dan kalium 1,1 mmol/kgBB. Untuk pasien berat badan 70 kg, ini setara dengan OLIMEL 2456 mL per hari, yang menghasilkan asupan asam amino 140 g, glukosa 270 g, dan lemak 98 g (contoh Kalori non-protein 2063 Kkal dan kalori total 2628 Kkal).

Normalnya, kecepatan rerata harus ditingkatkan secara bertahap selama 1 jam pertama dan kemudian disesuaikan dengan perhitungan dosis yang akan diberikan, asupan volume cairan dan waktu pemberian infus.

Untuk OLIMEL, kecepatan infus maksimum 1,8 mL/kgBB/jam, setara dengan 0,1 g/kgBB/jam asam amino, 0,19 g/kgBB/jam glukosa dan 0,07 g/kgBB/jam lemak.

Pada anak

Belum terdapat uji klinis pada anak

Metode dan waktu pemberian

Hanya untuk sekali pakai.

Direkomendasikan, setelah kantong dibuka, segera gunakan dan tidak disimpan untuk pemberian infus berikutnya.
Untuk petunjuk persiapan dan penanganan dari emulsi untuk infus lihat ruang Perhatian khusus untuk pembuangan dan penanganan lainnya.
Karena osmolaritasnya tinggi, OLIMEL hanya dapat diberikan melalui vena sentral.
Waktu pemberian infus yang direkomendasikan untuk 1 kantong nutrisi parenteral antara 12 dan 24 jam.
Produk hanya diberikan setelah *sekats* non-permanen antara 3 ruang telah dibuka dan isi dari 3 ruang telah dicampur.
Pastikan bahwa emulsi akhir untuk infus tidak menunjukkan adanya fase pemisahan.
Setelah isi kantong dibuka harus segera digunakan. Tidak boleh disimpan untuk pemberian infus berikutnya. Jangan hubungkan kembali seruang kantong yang sudah digunakan.
Jangan hubungkan secara bersamaan untuk menghindari kemungkinan terjadinya emboli yang terkandung di dalam kantong pertama.
Produk atau bahan limbah yang tidak terpakai dan semua peralatan yang digunakan harus dibuang.

Ekstravasasi
Tempat masuk kateter harus dimonitor secara teratur untuk mengetahui adanya tAnda ekstravasasi.
Jika terjadi ekstravasasi, pemberian harus segera dihentikan, lindungi tempat masuk kateter atau kanula untuk segera terapi pasien. Jika memungkinkan, aspirasi harus dilakukan melalui kateter/kanula dimasukkan, untuk mengurangi jumlah jumlah cairan di jaringan sebelum kateter/kanula dikeluarkan.

Tergantung dari produk yang terekstravasasi (termasuk produk yang telah dicampurkan dengan OLIMEL, jika memungkinkan) dan derajat cedera, harus segera dilakukan tindakan yang spesifik. Pilihan untuk terapi dapat dengan non-farmakologi, farmakologi dan/atau intervensi pembedahan. Pada kasus ekstravasasi yang luas, bedah plastik disarankan untuk dilakukan pada 72 jam pertama. Tempat ekstravasasi harus dimonitor sedikitnya tiap 4 jam selama 24 jam pertama, dilanjutkan 1 kali sehari.
Infus tidak dapat diberikan melalui vena sentral yang sama.

**Inkompatibilitas**

Inkompatibilitas dapat terjadi contohnya asam yang berlebihan (pH rendah) atau ketidaksesuaian kandungan kation divalen ($Ca^{2+}$ and $Mg^{2+}$), yang dapat menstabilkan emulsi lemak.

Seperti halnya campuran nutrisi parenteral, rasio kalsium dan fosfat harus dipertimbangkan. Penambahan kalsium dan fosfat yang berlebihan, khususnya dalam bentuk garam mineral, dapat menyebabkan pembentukan endapan kalsium fosfat.

OLIMEL mengandung ion kalsium yang menimbulkan risiko koagulasi tambahan pada antikoagulasi sitrat/endapan darah atau komponennya.

*Ceftriaxone* tidak dapat diberikan secara bersamaan dengan larutan intravena yang mengandung kalsium, termasuk OLIMEL, melalui selang infus yang sama (contoh: melalui Y-konektor) karena risiko terbentuknya endapan garam *Ceftriaxone*-kalsium.

Periksa kompatibilitas dengan larutan yang diberikan secara bersamaan melalui set yang sama, kateter atau kanula.

Jangan berikan sebelumnya, secara bersamaan dengan atau setelah darah melalui peralatan yang sama karena risiko terjadinya pseudoaglutinasi.

**PERHATIAN KHUSUS UNTUK PEMBUANGAN DAN PENANGANAN LAINNYA**

Periksa warna indikator oksigen, jika ada, sebelum membuka *overpouch*. Bandingkan dengan warna referensi yang dicetak di samping simbol OK dan digambarkan di area yang tercetak di label indikator.

Jangan gunakan produk jika warna indikator oksigen tidak sesuai dengan warna referensi yang dicetak di samping simbol OK.

Gambaran tentang langkah persiapan dalam pemberian OLIMEL tersedia di Gambar 1.
Untuk membuka lepaskan pelindung *overpouch*.
Buang oksigen *absorber*/*sachet* indikator oksigen.
Pastikan keutuhan dari kantong dan sekat non-permanen. Gunakan hanya jika kantong tidak rusak; jika sekat non-permanen utuh (contoh. tidak ada campuran kandungan dari 3 ruang); jika larutan asam amino dan glukosa jernih, tidak berwarna, atau sedikit kekuningan, dan bebas dari partikel yang terlihat; dan jika emulsi lemak homogen dengan gambaran seperti susu.

Pastikan produk pada suhu ruangan pada saat sekat non-permanen dibuka.
Secara manual gulung kantong, mulai dari ruang atas kantong (gantung terakhir). Sekat non-permanen akan hilang dari ruang samping *inlets*. Lanjutkan dengan menggulung kantong sampai sekat terbuka sepanjang kira-kira setengah dari panjangnya.
Campur dengan membalikkan kantong 3 kali.
Setelah pencampuran, campuran adalah emulsi homogen dengan gambaran seperti susu.
Kapasitas kantong cukup untuk penambahan seperti vitamin, elektrolit, dan mineral.

Penambahan apapun (termasuk vitamin) dapat dibuat menjadi campuran (setelah sekat non-permanen dibuka dan isi dari ketiga ruang dicampur).
Vitamin juga dapat ditambahkan kedalam ruang gluksoa sebelum campuran dilarutkan (sebelum membuka sekat non-permanen dan sebelum mencampur 3 ruang).
Ketika membuat penambahan pada formula yang mengandung elektrolit, sejumlah elektrolit yang sudah ada di dalam kantong harus diperhitungkan.

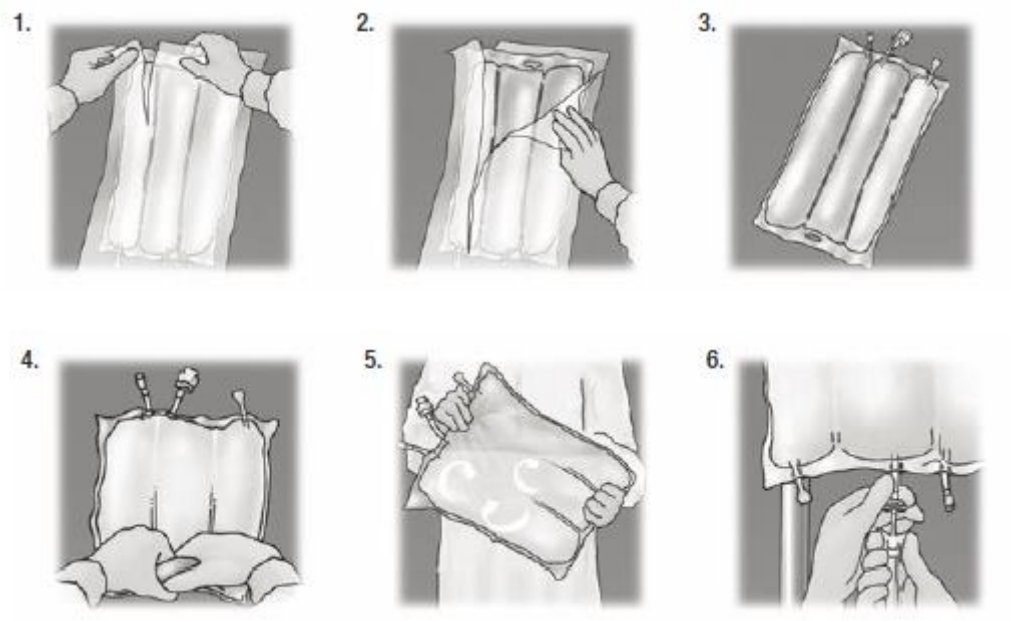
Penambahan harus dilakukan oleh petugas yang memenuhi syarat dalam kondisi aseptik.
OLIMEL dapat dilengkapi dengan elektrolit seperti di bawah ini:
Tiap 1000 mL :

| | Kadar yang sesuai | Penambahan maksimal | Kadar total maksimal |
|---|---|---|---|
| Natrium | 35 mmol | 115 mmol | 150 mmol |
| Kalium | 30 mmol | 120 mmol | 150 mmol |
| Magnesium | 4,0 mmol | 1,6 mmol | 5,6 mmol |
| Kalsium | 3,5 mmol | 1,5 (0,0[a]) mmol | 5,0 (3,5[a]) mmol |
| Fosfat inorganik | 0 mmol | 3,0 mmol | 3,0 mmol |
| Fosfat organik | 15 mmol[b] | 10 mmol | 25 mmol[b] |

a: Nilai sesuai dengan penambahan fosfat inorganik.
b: Termasuk fosfat yang tersedia melalui emulsi lemak.

Mineral dan vitamin:
Stabilitas telah ditunjukkan dengan sediaan vitamin dan mineral komersial yang ada (mengandung besi sampai 1 mg).
Kompatibilitas untuk penambahan lainnya sesuai dengan permintaan.
Ketika membuat penambahan, osmolaritas akhir dari campuran harus diukur sebelum pemberian melalui vena perifer.
Untuk melakukan penambahan:
- Kondisi aseptik harus diperhatikan.
- Siapkan tempat suntikan kantong.
- Tusuk tempat suntikan dan suntikan zat tambahan dengan menggunakan jarum suntik atau perangkat pencampuran.
- Campur isi dari kantong dan zat tambahan.

Persiapan untuk infus.
Kondisi aseptik harus diperhatikan.
Singkirkan kantong.
Hilangkan pelindung plastik dari tempat pemberian.
Masukkan dengan lembut ujung infus set ke tempat pemberian.




Keterangan gambar:

1. Robek ruang atas untuk membuka *overpouch*.
2. Tarik ruang depan *overpouch* untuk mengeluarkan kantong OLIMEL. Buang *overpouch* dan *sachet* oksigen absorber.
3. Tempatkan kantong secara rata horisontal dan di permukaan yang bersih dengan pegangan di depan Anda.
4. Pegang area penggantung untuk menghilangkan cairan dari ruang atas kantong. Gulung ruang atas kantong secara perlahan sampai sekat terbuka seluruhnya (sekitar setengahnya).
5. Campur dengan membalikkan kantong ke atas-bawah sedikitnya 3 kali.
6. Gantung kantong. Putar pelindung dari tempat pemberian luar. Pasang secara perlahan *spike* ke konektor.

Reg. No. DKI1710700349A1

Simpan pada suhu di bawah 30°C

Diproduksi oleh :

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Bekasi – Indonesia

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