SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Finomel emulsion for infusion

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Finomel is presented in a 3-compartment plastic bag. Each bag contains a sterile non-pyrogenic combination of a 42% glucose solution, a 10% amino acid solution with electrolytes, and a 20% lipid emulsion.

Composition of the reconstituted emulsion after mixing the content of the 3 compartments is provided in the table below:

Active Substance	**1085 mL**	**1435 mL**	**1820 mL**
Fish oil, rich in omega-3-acids	8.24 g	10.92 g	13.84 g
Olive oil, refined	10.30 g	13.65 g	17.30 g
Soya-bean oil, refined	12.36 g	16.38 g	20.76 g
Medium-chain triglycerides	10.30 g	13.65 g	17.30 g
Alanine	11.41 g	15.09 g	19.13 g
Arginine	6.34 g	8.38 g	10.63 g
Glycine	5.68 g	7.51 g	9.52 g
Histidine	2.64 g	3.50 g	4.44 g
Isoleucine	3.31 g	4.37 g	5.54 g
Leucine	4.02 g	5.32 g	6.75 g
Lysine *(as Lysine hydrochloride)*	3.20 g *(3.99 g)*	4.23 g *(5.29 g)*	5.36 g *(6.70 g)*
Methionine	2.20 g	2.92 g	3.70 g
Phenylalanine	3.09 g	4.08 g	5.17 g
Proline	3.75 g	4.96 g	6.28 g
Serine	2.76 g	3.65 g	4.62 g
Threonine	2.31 g	3.06 g	3.88 g
Tryptophan	0.99 g	1.31 g	1.66 g
Tyrosine	0.22 g	0.29 g	0.37 g
Valine	3.20 g	4.23 g	5.36 g
Sodium acetate trihydrate	3.10 g	4.10 g	5.19 g

Active Substance	1085 mL	1435 mL	1820 mL
Potassium chloride	2.47 g	3.27 g	4.14 g
Calcium chloride dihydrate	0.41 g	0.54 g	0.68 g
Magnesium sulfate heptahydrate	1.36 g	1.80 g	2.28 g
Sodium glycerophosphate, hydrated	3.26 g	4.32 g	5.47 g
Zinc sulfate heptahydrate	0.013 g	0.017 g	0.021 g
Glucose *(as Glucose monohydrate)*	137.8 g *(151.5 g)*	181.9 g *(200.0 g)*	231.0 g *(254.1 g)*

Nutritional intakes of reconstituted emulsion, for each bag size:

	1085 mL	1435 mL	1820 mL
Nitrogen (g)	9.1	12.0	15.3
Amino acids (g)	55	73	92
Glucose (g)	138	182	231
Lipids[a] (g)	44	58	73
Energy:			
Total calories (kcal)	1184	1567	1988
Non-protein calories (kcal)	964	1276	1619
Glucose calories (kcal)[b]	571	755	958
Lipid calories (kcal)[c]	393	521	661
Non-protein calories / nitrogen ratio (kcal/g)	106	106	106
Glucose / Lipid calories ratio	59/41	59/41	59/41
Lipid / Total calories	33%	33%	33%
Electrolytes:			
Sodium (mmol)	44.1	58.3	73.9
Potassium (mmol)	33.1	43.8	55.5
Magnesium (mmol)	5.5	7.3	9.3
Calcium (mmol)	2.8	3.7	4.7
Phosphorus (mmol)	10.7/13.8[d]	14.1/18.3[d]	17.9/23.1[d]
Acetate (mmol)	79.5	105	133
Chloride (mmol)	60.5	80.1	102
Sulfate (mmol)	5.6	7.4	9.3
Zinc (mmol)	0.04	0.06	0.07
pH (approx.)	6.0	6.0	6.0
Osmolarity (approx.)	1440	1440	1440

	1085 mL	1435 mL	1820 mL
(mOsm/L)			

[a] As sum of oil and phospholipids content.

[a] As sum of glucose and glycerol content in g x 4 kcal/g.

[b] As sum of oil and phospholipids content in g x 9 kcal/g.

[c] Without phosphorus from lipid emulsion / with phosphorus from lipid emulsion.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Emulsion for infusion.

Appearance of the drug product before reconstitution:

- The glucose and amino acid solutions are clear and colorless to slightly yellow and free from particles.
- The lipid emulsion is white and homogeneous.

After mixing of the 3 chambers the appearance of the product is a white emulsion

Osmolarity: approx. 1440 mosmol/l
pH after mixing: approx. 6.0

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Finomel is indicated for parenteral nutrition in adult patients when oral or enteral nutrition is impossible, insufficient or contraindicated.

4.2 Posology and method of administration

For single use only.

It is recommended that after opening the bag, the content should be used immediately, and not stored for subsequent infusion.

See section 6.6 for instructions on the administration, preparation and handling of the product.

Posology

The dosage should be individualized depending on energy expenditure, the patient's clinical status, body weight, and ability to metabolize constituents of Finomel, as well as additional energy or proteins given orally/enterally. Therefore, the bag size should be chosen accordingly.

The average daily requirements for adults are:

- In patients with normal nutritional state or in conditions with mild catabolic stress: 0.6-0.9 g amino acids/kg bw/day (0.10-0.15 g nitrogen/kg bw/day).

- In patients with moderate to high metabolic stress with or without malnutrition: 0.9-1.6 g amino acids/kg bw/day (0.15-0.25 g nitrogen/kg bw/day).

- In patients with special conditions (e.g. burns or marked anabolism) the nitrogen need may be even higher.

The maximum daily dose varies with the clinical condition of the patient and may change from day to day.

The flow rate should be increased gradually during the first hour.
The administration flow rate must be adjusted taking into account the dose being administered, the daily volume intake and the duration of the infusion. (See section 4.9).

The recommended infusion period is 14-24 hours.

The dosage range of 13-31 ml/kg bw/day will provide 0.7-1.6 g amino acids/kg bw/day (corresponds to 0.11-0.26 g nitrogen/kg bw/day) and 14-33 kcal/kg bw/day of total energy (11-27 kcal/kg bw/day of non-protein energy).

The maximum infusion rate for glucose is 0.25 g/kg bw/h, for amino acids 0.1 g/kg bw/h, and for lipids 0.15 g/kg bw/h.

The infusion rate should not exceed 2.0 ml/kg bw/h (corresponding to 0.10 g amino acids, 0.25 g glucose and 0.08 g lipids/kg bw/h).

The recommended maximum daily dose is 35 ml/kg bw/day which will provide 1.8 g amino acids/kg bw/day (corresponding to 0.29 g nitrogen/kg bw/day), 4.5 g glucose/kg bw/day, 1.40 g lipids/kg bw/day and a total energy content of 38 kcal/kg bw/day (corresponding to 30 kcal/kg bw/day of non-protein energy).

Paediatric population

The safety and efficacy of Finomel in children and adolescent less than 18 years of age has not been established.
No data are available.

Patients with renal/hepatic impairment

The dosage should be individualized depending on the patient's clinical status (see section 4.4).

Method of administration

Intravenous use, infusion into a central vein.

For instructions on reconstitution of the medicinal product before administration, see section 6.6.

For information on mixing with other infusions/blood before or during administration, see section 4.5 and 6.6.

4.3 Contraindications

- Hypersensitivity to fish-, egg-, soya- peanut- proteins, corn/corn products (see section 4.4), or to any of the active substances or excipients listed in section 6.1
- Severe hyperlipidemia
- Severe hepatic impairment
- Severe blood coagulation disorders
- Congenital abnormalities of amino acid metabolism
- Severe renal impairment without access to hemofiltration or dialysis
- Uncontrolled hyperglycemia
- Pathologically elevated serum levels of any of the included electrolytes
- General contraindications to infusion therapy: acute pulmonary oedema, hyperhydration, and decompensated cardiac insufficiency
- Unstable conditions (e.g. severe post-traumatic conditions, uncompensated diabetes mellitus, acute myocardial infarction, stroke, embolism, metabolic acidosis, severe sepsis, hypotonic dehydration and hyperosmolar coma)

4.4 Special warnings and precautions for use

Must only be administered through a central vein.

Hypersensitivity or anaphylactic reaction
The infusion must be stopped immediately if any signs or symptoms of an allergic reaction (such as fever, shivering, rash or dyspnea) develop.

Finomel contains soya-bean oil, fish oil and egg phospholipids, which may rarely cause allergic reactions. Cross allergic reaction has been observed between soybean and peanut.

Finomel contains glucose derived from corn, which may cause hypersensitivity reactions in patients with allergy to corn or corn products (see section 4.3).

Pulmonary vascular precipitates
Pulmonary vascular precipitates causing pulmonary vascular emboli and pulmonary distress have been reported in patients receiving parenteral nutrition. In some cases, fatal outcomes have 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 in vivo precipitate formation has also been 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.

Infection and sepsis
Since an increased risk of infection is associated with the use of any vein, strict aseptic precautions should be taken to avoid any contamination during catheter insertion and manipulation.

Fat overload syndrome
"Fat overload syndrome" has been reported with similar products. This may be caused by inappropriate administration (e.g., overdose and/or infusion rate higher than recommended); however, the signs and symptoms of this syndrome may also occur when the product is administered according to instructions. The reduced or limited ability to metabolize the lipids contained in Finomel accompanied by prolonged plasma clearance may result in a fat overload syndrome. This syndrome is associated with a sudden deterioration in the patient's clinical condition and is characterized by findings such as fever, anaemia, leucopoenia, thrombocytopenia, coagulation disorders, hyperlipidaemia, liver fatty infiltration (hepatomegaly), deteriorating liver function, and central nervous system manifestations (e.g., coma). The syndrome is usually reversible when the infusion of the lipid emulsion is stopped.

Use in patients with impaired lipid metabolism.
Monitor the patient's capacity to eliminate lipids by checking the triglyceride levels. The concentration of triglycerides in serum should not exceed 4.6 mmol/l during infusion.
Use with caution in conditions of impaired lipid metabolism, which may occur in patients with renal failure, diabetes mellitus, pancreatitis, impaired liver function, hypothyroidism and sepsis.

Serum glucose, electrolytes and osmolarity as well as fluid balance, acid-base status and liver enzyme tests should be monitored.

Refeeding syndrome
Refeeding severely undernourished patients may result in the refeeding syndrome that is characterized by the shift of potassium, phosphorus, and magnesium intracellularly as the patient becomes anabolic. Thiamine deficiency and fluid retention may also develop. Careful monitoring and slowly increasing nutrient intakes while avoiding

overfeeding can prevent these complications. This syndrome has been reported with similar products.

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 in this patient group, together with close monitoring and appropriate adjustments of fluid, electrolytes, minerals and vitamins.

Parenteral nutrition associated liver disease
Use with caution in patients with hepatic impairment, including cholestasis and/or elevated liver enzymes. Liver function parameters should be closely monitored.

Hyperglycemia
If hyperglycemia occurs, it should be treated according to the clinical situation either by appropriate insulin administration and/or adjustment of the infusion rate (see section 4.9).

Renal impairment
Use with caution in patients with renal impairment. The phosphate, magnesium, and potassium intake should be carefully controlled to prevent hyperphosphatemia, hypermagnesemia and/or hyperkalemia.
Disturbances of the electrolyte and fluid balance (e.g. abnormally high or low serum levels of the electrolytes) should be corrected before starting the infusion.

Water and electrolytes balance
Monitor water and electrolyte balance, serum osmolarity, serum triglycerides, acid-base balance, blood glucose, liver and kidney function, and blood count, including platelets and coagulation parameters throughout treatment.

Lactic acidosis
Use with caution in patients with lactic acidosis, insufficient cellular oxygen supply and/or increased serum osmolarity.

Long-term use
Intravenous infusion of amino acids is accompanied by increased urinary excretion of the trace elements, in particular copper and zinc. This should be considered in the dosing of trace elements, especially during long-term intravenous nutrition. The quantity of zinc administered with Finomel should be taken into account.

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

Excess of amino acid infusion
As with other amino acid solutions, the amino acid content in Finomel may cause undesirable effects when the recommended infusion rate is exceeded. These effects are nausea, vomiting, shivering and sweating. Amino acid infusion may also cause a rise in body temperature. With

an impaired renal function, increased levels of nitrogen containing metabolites (e.g., creatinine, urea) may occur.

Electrolyte retention
Finomel should be given with caution to patients with a tendency towards electrolyte retention. Special clinical monitoring is required at the beginning of any intravenous infusion. Should any abnormal sign occur, the infusion must be stopped.

Excessive PN administration
To avoid risks associated with too rapid infusion rates, it is recommended to use a continuous and well-controlled infusion, if possible by using a volumetric pump (see also section 4.9).

Interference with laboratory tests
The lipids contained in this emulsion may interfere with the results of certain laboratory tests (see section 4.5).

Paediatric population
There have been no studies performed with Finomel in the paediatric population.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed with Finomel.

Finomel should not be administered simultaneously with blood through the same infusion tubing due to the risk of pseudoagglutination.

Ceftriaxone must not be administered simultaneously with intravenous calcium-containing solutions, including Finomel, through the same infusion line (e.g., via Y-connector) 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 between infusions with a compatible fluid.

Soya-bean oil has a natural content of vitamin K_1. However, the concentration in Finomel is so low that it is not expected to significantly influence the coagulation process in patients treated with coumarin derivatives.

The lipids contained in this emulsion may interfere with the results of certain laboratory tests (for example, bilirubin, lactate dehydrogenase, oxygen saturation, blood hemoglobin) 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) (see section 4.4).

4.6 Fertility, pregnancy and lactation

Pregnancy

There are no data from the use of Finomel in pregnant women. Parenteral nutrition may become necessary during pregnancy. Finomel should only be given to pregnant women after careful consideration.

Breast-feeding

There is insufficient information on the excretion of Finomel components/metabolites in human milk. Parenteral nutrition may become necessary during breast-feeding. Finomel should only be given to breast-feeding women after careful consideration.

Fertility

No adequate data are available.

4.7 Effects on ability to drive and use machines

Not relevant

4.8 Undesirable effects

The following adverse reactions have been reported with other similar products. The frequency of these events cannot be estimated from available data:

System Organ Class (SOC)	**Preferred MedDRA term**
Immune system disorders	Hypersensitivity
Metabolism and nutrition disorders	Refeeding syndrome, Hyperglycemia
Nervous system disorders	Dizziness, Headache
Vascular disorders	Thrombophlebitis
Respiratory, thoracic and mediastinal disorders	Pulmonary embolism (see section 4.4) Respiratory distress (see section 4.4) Dyspnea
Gastrointestinal disorders	Nausea, Vomiting
General disorders and administration site conditions	Pyrexia, Extravasation
Investigations	Hepatic enzyme increased
Injury, poisoning and procedural complications	Fat overload syndrome, Parenteral nutrition associated liver disease

Description of selected adverse reactions

- Fat overload syndrome

Fat overload syndrome has been reported with similar products. This may be caused by inappropriate administration (e.g. overdose and/or infusion rate higher than recommended, see section 4.9); however, the signs and symptoms of this syndrome may also occur at the start of an infusion when the product is administered according to instructions. The reduced or limited ability to metabolize the lipids contained in Finomel accompanied by prolonged plasma clearance may result in a “fat overload syndrome” (see section 4.4).

- Refeeding syndrome

Refeeding severely undernourished patients may result in the refeeding syndrome that is characterized by the shift of potassium, phosphorus, and magnesium intracellularly as the patient becomes anabolic. Thiamine deficiency and fluid retention may also develop.
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.
For specific recommendation, refer to section 4.4.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme.
Website: www.mhra.gov.uk/yellowcard

4.9 Overdose

In the event of an overdose, nausea, vomiting, chills, hyperglycemia, and electrolyte disturbances and signs of hypervolemia or acidosis may occur. In such situations the infusion must be stopped immediately (see section 4.4).

If hyperglycemia occurs, it should be treated according to the clinical situation either by appropriate insulin administration and/or adjustment of the infusion rate. Additionally, overdose might cause fluid overload, electrolyte imbalances and hyperosmolality.

If symptoms persist after discontinuing infusion, hemodialysis, hemofiltration or hemodiafiltration may be considered.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Solutions for parenteral nutrition/combination, ATC code: B05BA10

Mechanism of action

Lipid emulsion

The lipid component of Finomel is a lipid mixture composed of a combination of four different oil sources: soya-bean oil (30%), medium chain triglyceride oil (25%), olive oil (25%) and fish oil (20%).

- Soya-bean oil has a high content of essential fatty acids. The omega-6 fatty acid linoleic acid is the most abundant (approx. 55-60%). Alpha-linolenic acid, an omega-3 fatty acid, constitutes about 8%. This part of Finomel provides the necessary amount of essential fatty acids.

- Medium-chain fatty acids are rapidly oxidized and provide the body with a form of immediately available energy.

- Olive oil mainly provides energy in the form of mono-unsaturated fatty acids, which are much less prone to peroxidation than the corresponding amount of polyunsaturated fatty acids.

- Fish oil is characterized by a high content of eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA). DHA is an important structural component of cell membranes, whereas EPA is a precursor of eicosanoids such as prostaglandines, thromboxanes and leucotrienes.

Amino acids and electrolytes

The amino acids, constituents of protein in ordinary food, are utilized for tissue protein synthesis and any surplus is channelled to a number of metabolic pathways. Studies have shown a thermogenic effect of amino acid infusion.

Glucose

Glucose should serve as a source of energy and contributes to the maintenance of the normal nutritional status.

5.2 Pharmacokinetic properties

Lipid emulsion
The individual triglycerides in combination lipid emulsions have different clearance rate but data for similar combination lipid emulsions has showed that these mixtures are eliminated faster than long chain triglyceride (LCT) emulsions. Olive oil has the slowest clearance rate of the components (somewhat slower than LCT) and medium chain triglycerides (MCT) the fastest. Fish oil in a mixture with LCT has the same clearance rate as LCT alone.

Amino acids and electrolytes
The principal pharmacokinetic properties of the infused amino acids and electrolytes are essentially the same as for amino acids and electrolytes supplied by ordinary food. However, the amino acids of dietary protein first enter the portal vein and then the systemic circulation, while intravenously infused amino acids reach the systemic circulation directly.

5.3 Preclinical safety data

No conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential or toxicity to reproduction and development have been performed with Finomel.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Finomel contains the following excipients:
Acetic acid, glacial (pH adjuster)
Hydrochloric acid (pH adjuster)
Egg phospholipids for injection
Glycerol
Sodium oleate
All-rac-α-Tocopherol
Sodium hydroxide (pH adjuster)
Water for injections

6.2 Incompatibilities

This medicinal product must not be mixed with other medicinal products for which compatibility has not been documented (see section 6.6).

Ceftriaxone must not be mixed or administered simultaneously with intravenous calcium containing solutions, including Finomel (see section 4.5).

Finomel should not be administered simultaneously with blood through the same infusion tubing (see section 4.5).

6.3 Shelf life

2 years.

After reconstitution:
It is recommended to use the product immediately after the non-permanent seals between the three chambers have been opened. However stability data of the

reconstituted mixtures supports 7 days between 2°C and 8°C followed by 48 hours at 25°C.

After supplementation (electrolytes, trace elements, vitamins; see section 6.6):
For specific admixtures, in-use stability has been demonstrated for 7 days between 2°C and 8°C followed by 48 hours at 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 to 8°C, unless addition of supplements has taken place in controlled and validated aseptic conditions.

6.4 Special precautions for storage

Do not freeze
Store in the original overpouch

For storage conditions after reconstitution of the medicinal product, see section 6.3

6.5 Nature and contents of container

The three-chamber bag is a non-PVC multi-layer plastic bag, with 3 port tubes:
One medication site is on the glucose compartment, one infusion site on the amino acid compartment and one port tube on the lipid compartment which is sealed-off to prevent any addition to this chamber.

The inner layer of the bag material in contact with the solution is made of a blend of polyolefin/polyolefinic elastomer copolymers. Other layers are made of polypropylene, and of a blend of polyolefin/polyolefinic elastomer copolymers.

The Product is available in pack of:

4x1085 ml, 4x1435 ml, 4x1820 ml

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

To open:

- Remove the protective overpouch.
- Discard the oxygen absorber sachet.

- Use only if the bag is not damaged, the non-permanent seals are intact (i.e., no content mixture of any of the three chambers), the solution in the amino acids chamber and the solution in the glucose chamber are clear, colorless, or slightly yellow, free of visible particles, and the lipid emulsion is a homogeneous liquid with a milky appearance.

To mix the chambers:

- 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.

After removing the protective cap from the medication port, one can add compatible additives via the medication port.

No additions to the bag should be made without first checking the compatibility, as the formation of precipitates or destabilization of the lipid emulsion could result in vascular occlusion.

Addition should be made aseptically

Finomel can be mixed with the following additives:

- Multi-vitamin preparations
- Multi-trace element preparations
- Selenium
- Zinc
- Sodium salt
- Potassium salt
- Magnesium salt
- Calcium salt
- Phosphate salt

The compatibility indicative table below shows possible additions of multi-trace element product such as Nutryelt and multi-vitamin product such as Cernevit and generics of electrolytes and trace elements in defined quantities. The addition of clinically needed electrolytes and trace elements should take into account the amounts already included in the initial bag formulation.

Additive	**Total content after addition for all bag sizes of Finomel**
Nutryelt (Composition per vial: Zinc 153 µmol; Copper 4.7 µmol; Manganese 1.0 µmol; Fluorine 50 µmol; Iodine 1.0 µmol; Selenium 0.9 µmol; Molybdenum 0.21 µmol; Chromium 0.19 µmol; Iron 18 µmol)	2 vials [a]/bag
Cernevit (Composition per vial: Vit. A (as Retinol palmitate) 3500 IU, Vit. D3 (Cholecalciferol) 220 IU, Vit. E	2 vials [b]/bag

(Alpha-tocopherol) 11.2 IU, Vit. C (Ascorbic acid) 125 mg, Vit. B1 (Thiamine) 3.51 mg, Vit. B2 (Riboflavin) 4.14 mg, Vit. B6 (Pyridoxine) 4.53 mg, Vit. B12 (Cyanocobalamin) 6 µg, Vit. B9 (Folic acid) 414 µg, Vit. B5 (Pantothenic acid) 17.25 mg, Vit. B8 (Biotin) 69 µg, Vit. PP (Nicotinamide) 46mg)	
Sodium	138 mmol/L
Potassium	138 mmol/L
Magnesium	5 mmol/L
Calcium	4.6 mmol/L
Phosphate (organic such as sodium glycerophosphate) Or Phosphate (mineral such as potassium phosphate)	18.5 mmol/L 5.5 mmol/L
Selenium	7.6 µmol/L
Zinc	0.31 mmol/L
[a] Volume of vial: 10mL concentrate solution [b] Volume of vial: 5 mL lyophilisate	

Compatibility may vary between products from different sources and health care professionals are advised to carry out appropriate checks when mixing Finomel with other parenteral solutions.

Mix the contents of the bag thoroughly and visually inspect the mixture. There should be no signs of emulsion phase separation. The mixture is a milky white homogenous emulsion.

When making additions, the final osmolarity of the admixture must be assessed.

Remove the protector cap from the infusion port and attach the infusion set. Hang the bag on an infusion stand and carry out infusion using the standard technique.

After opening the bag, content should be used immediately, and should not 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 air embolism.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Baxter Healthcare Ltd
Caxton Way, Thetford,
Norfolk, IP24 3SE
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 00116/0661

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

28/12/2018

10 DATE OF REVISION OF THE TEXT

28/12/2018