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Package leaflet : Information for the user

FINOMEL PERI EMULSION FOR INFUSION

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What FINOMEL PERI is and what it is used for
2. What you need to know before you use FINOMEL PERI
3. How to use FINOMEL PERI
4. Possible side effects
5. How to store FINOMEL PERI
6. Contents of the pack and other information

1. What FINOMEL PERI is and what it is used for

FINOMEL PERI contains amino acids (components used to build proteins), glucose (carbohydrates), lipids (fat) and salts (electrolytes).
FINOMEL PERI is used to provide nutrition to adults when normal feeding by mouth is insufiscient or not suitable.

2. What you need to know before you use FINOMEL PERI

Do not use FINOMEL PERI:
- If you are allergic to fish, egg, soya-bean, peanut proteins, or corn/corn products (see also section "Warnings and precations" below), or any of the other ingredients of this medicine (listed in section 6).
- If you have high level of fats in your blood
- If have severe problems with your liver
- If you have blood coagulation problems
- If you have a disorder whereby amino acids cannot be processed by the body
- If you have severe problems with your kidneys
- If you have too much sugar in your blood
- If you have an abnormally high amount of any of the electrolytes (sodium, potassium, magnesium, calcium and/or phosphorus) in your blood
- If you have problems receiving large volumes of liquids in your veins such as acute pulmonary oedema, hyperhydration and decompensated heart problems
- If you have any acute and severe health problem such as severe post-traumatic conditions, uncontrolled diabetes mellitus, acute myocardial infarction, stroke, embolism, metabolic acidosis, severe sepsis (bacteria in the blood), hypotonic dehydration and hyperosmolar coma

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

Warnings and precautions
Talk to your doctor or nurse before using FINOMEL PERI if you have:
- A severe kidney problem. You also must inform your doctor if you are on dialysis (artificial kidney) or if you have another form of blood cleaning treatment
- A severe liver problem
- A blood coagulation problem
- Adrenal glands that are not working properly (adrenal insufficiency). The adrenal glands are triangle-shaped glands located on top of your kidneys.
- Heart failure
- Lung disease
- A build-up of water in your body (hyperhydration)
- Not enough water in your body (dehydration)
- High blood sugar (diabetes mellitus) that you are not being treated for
- A heart attack or shock due to a sudden heart failure
- A severe metabolic acidosis (when the blood is too acid)
- A severe infection (sepsis)

If any abnormal signs or symptoms of an allergic reaction develop, such as fever, chills, skin rashes or difficulty in breathing, the infusion will be stopped immediately. This medicinal product contains fish oil, soya-bean oil, egg phosphatide proteins and glucose derived from corn that may cause hypersensitivity reactions. Cross-allergic reactions between soya-bean and peanut proteins have been observed.

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

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

There is a particular risk of infection or sepsis (bacteria or their toxins in the blood) when a tube (intravenous catheter) is placed in your vein. Your doctor will carefully watch you for any signs of infection. Using "aseptic technique" ("germ free") when placing and maintaining the catheter and when making the nutritional formula can reduce the risk of infection.

Fat overload syndrome has been reported with similar products. The reduced or limited ability of the body to remove the fats contained in FINOMEL PERI may result in a "fat overload syndrome" (see section 4 – Possible Side Effects).

If you are severely malnourished such that you need to receive feedings by vein, it is recommended that parenteral nutrition is started slowly and carefully.

Additional monitoring tests
The balance of water and electrolytes in your body and metabolic disorders should be corrected before starting the infusion. To check the effectiveness and ongoing safety of the administration, your doctor may perform clinical and laboratory tests while you are receiving this medicine. Your doctor will monitor your condition and may change the dosage or give you additional medication.

Children and adolescents
At the moment, there is no experience of the use of FINOMEL PERI in children and adolescents.

Other medicines and FINOMEL PERI
Tell your doctor or nurse if you are taking, have recently taken or might take any other medicines.

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

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

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

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before you're given this medicine. There is no data from the use of FINOMEL PERI in pregnancy or breast-feeding women. The use of this medicine during pregnancy and breast-feeding may be considered if necessary as advised by your doctor.

Driving and using machines
Not relevant as the medicine is given at the hospital.

3. How to use FINOMEL PERI

Always use this medicine exactly as your doctor has told you. Check with your doctor if you are not sure. This medicine is administered by intravenous infusion (drip) through a small tube directly into a vein. Your doctor will decide on the dose for you individually depending on your body weight and function. FINOMEL PERI will be given to you by a health care professional.

Use in children
Safety and efficacy in children and adolescents less than 18 years have not been established.

If you use more FINOMEL PERI than you should
It is unlikely that you will receive too much medicine as FINOMEL PERI is given to you by a healthcare professional.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects have been reported at an unknown frequency:
- Hypersensitivity reactions (that can give symptoms like swelling, fever, fall in blood pressure, skin rashes, wheals (raised red areas), flushing, headache).
- Refeeding syndrome (a disease that develop when receiving feeding after long periods of fasting)
- Elevated blood sugar levels (Hyperglycemia)
- Dizziness
- Headache
- Inflammation of the veins (Thrombophlebitis)
- Pulmonary embolism
- Difficulty in breathing
- Nausea
- Vomitting
- A slightly raised body temperature
- High blood (plasma) levels of coumpounds from the liver
- Fat overload syndrome
- Leakage of the infusion to the surrounding tissue (extravasation)

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

United Kingdom : via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

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

5. How to store FINOMEL PERI

Keep this medicine out of the sight and reach of children.
Store in the overpouch. Do not freeze.

Do not use this medicine after the expiry date which is stated on the label on the bag and carton after EXP. The expiry date refers to the last day of that month.

Do not use this medicine if you notice visible particles in the solution or if the bag is damaged.

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

6. Contents of the pack and other information

What FINOMEL PERI contains
- The active substances are

	g per 1000 ml		g per 1000 ml
Alanine	6.52	Tyrosine	0.13
Arginine	3.62	Valine	1.83
Glycine	3.24	Sodium acetate trihydrate	1.77
Histidine	1.51	Potassium chloride	1.41
Isoleucine	1.89	Calcium chloride dihydrate	0.23
Leucine	2.30	Magnesium sulfate heptahydrate	0.78
Lysine (as hydrochloride)	2.28	Sodium glycerophosphate hydrated	1.87
Methionine	1.26	Zinc sulphate heptahydrate	0.007
Phenylalanine	1.76	Glucose (as monohydrate)	77.8
Proline	2.14	Soya-bean oil, refined	8.46
Serine	1.58	Olive oil, refined	7.05
Threonine	1.32	Medium-chain triglycerides	7.05
Tryptophan	0.57	Fish oil, rich in omega-3-acids	5.64

- The other ingredients are: Glacial acetic acid, hydrochloric acid, egg phospholipids, glycerol, sodium oleate, all-rac-α-Tocopherol, sodium hydroxide, water for injections.

What FINOMEL PERI looks like and contents of the pack
The glucose and amino acid solutions are clear and colourless to slightly yellow, and free from particles. The lipid emulsion is white and homogenous.

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

Pack sizes
4x1085ml
4x1450ml
4x2020ml

Marketing Authorisation Holder and Manufacturer
United Kingdom:
Baxter Healthcare Ltd
Caxton Way, Thetford,
Norfolk, IP24 3SE
United Kingdom

Ireland:
Baxter Holding B.V.
Kobaltweg 49,
3542CE Utrecht,
Netherlands

Manufacturer:
Baxter SA
Boulevard René Branquart 80
7860 Lessines
Belgium

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

Austria, Czech Republic, Germany, Greece, Ireland, Poland, Spain, United Kingdom	FINOMEL PERI
Belgium, Luxembourg, Netherlands	Peri-Omegomel
Denmark, Finland, Iceland, Norway, Sweden	Finomel Peri
France	FOSOMELPERI
Italy	Finomel

This leaflet was last revised in March 2019.
For information about FINOMEL PERI or to request this leaflet in formats such as audio or large print please contact the Marketing Authorisation Holder: Tel: +44 1635 206345.

The following information is intended for healthcare professionals only:

A. QUALITATIVE AND QUANTITATIVE COMPOSITION

FINOMEL PERI is presented in a 3-compartment plastic bag. Each bag contains a sterile non-pyrogenic combination of a 13% 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	1450 mL	2020 mL
Fish oil, rich in omega-3-acids	6.12 g	8.16 g	11.40 g
Olive oil, refined	7.65 g	10.20 g	14.25 g
Soya-bean oil, refined	9.18 g	12.24 g	17.10 g
Medium-chain triglycerides	7.65 g	10.20 g	14.25 g
Alanine	7.08 g	9.46 g	13.17 g
Arginine	3.93 g	5.26 g	7.31 g
Glycine	3.52 g	4.71 g	6.55 g
Histidine	1.64 g	2.19 g	3.05 g
Isoleucine	2.05 g	2.74 g	3.82 g
Leucine	2.50 g	3.34 g	4.64 g
Lysine	1.98 g	2.65 g	3.69 g
(as Lysine hydrochloride)	*(2.48 g)*	*(3.31 g)*	*(4.61 g)*
Methionine	1.37 g	1.83 g	2.54 g
Phenylalanine	1.92 g	2.56 g	3.56 g
Proline	2.33 g	3.11 g	4.32 g
Serine	1.71 g	2.29 g	3.18 g
Threonine	1.44 g	1.92 g	2.67 g
Tryptophan	0.62 g	0.82 g	1.14 g
Tyrosine	0.14 g	0.18 g	0.25 g
Valine	1.98 g	2.65 g	3.69 g
Sodium acetate trihydrate	1.92 g	2.57 g	3.57 g
Potassium chloride	1.53 g	2.05 g	2.85 g
Calcium chloride dihydrate	0.25 g	0.34 g	0.47 g
Magnesium sulfate heptahydrate	0.84 g	1.13 g	1.57 g
Sodium glycerophosphate, hydrated	2.03 g	2.71 g	3.77 g
Zinc sulfate heptahydrate	0.008 g	0.011 g	0.015 g
Glucose anhydrous	76.7 g	102.6 g	142.9 g
(as Glucose monohydrate)	*(84.4 g)*	*(112.8 g)*	*(157.2 g)*

B. POSOLOGY AND METHOD OF ADMINISTRATION

Posology
The dosage should be individualized depending on energy expenditure, the patient's clinical status, body weight, and ability to metabolize constituents of FINOMEL PERI, 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.
The recommended infusion period is 14-24 hours.

The dosage range of 20 ml – 40 ml/kg bw/day corresponds to 0.6-1.3 g amino acids/kg bw/day (0.10-0.21 g nitrogen/kg bw/day) and 14-27 kcal/kg bw/day of total energy (11-22 kcal/kg bw/day of non-protein energy).

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

The infusion rate should not exceed 3.0 ml/kg bw/h (corresponding to 0.09 g amino acids, 0.21 g glucose and 0.09 g lipids/kg bw/h).

The recommended maximum daily dose is 40 ml/kg bw/day, which will provide 1.3 g amino acids/kg bw/day (corresponding to 0.21 g nitrogen/kg bw/day), 2.8 g glucose/kg bw/day, 1.2 g lipids/kg bw/day and a total energy of 27 kcal/kg bw/day (corresponding to 22 kcal/kg bw/day of non-protein energy).

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

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

Method of administration
Intravenous use, infusion into a peripheral or central vein.

For instructions on reconstitution of the medicinal product before administration, see section E. Special precautions for disposal and other handling.

If peripheral veins are used for infusions, the osmolality of solutions should be considered, as thrombophlebitis may occur. The catheter insertion site should be evaluated daily for local signs of thrombophlebitis.

For information on mixing with other infusions/blood before or during administration, see section C. Incompatibilities.

C. INCOMPATIBILITIES

This medicinal product must not be mixed with other medicinal products for which compatibility has not been documented.

Ceftriaxone must not be mixed or administered simultaneously with intravenous calcium containing solutions, including FINOMEL PERI.

FINOMEL PERI should not be administered simultaneously with blood through the same infusion tubing.

The following information is intended for healthcare professionals only:

D. 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.

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.

E. SPECIAL PRECAUTIONS FOR DISPOSAL AND OTHER HANDLING

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.

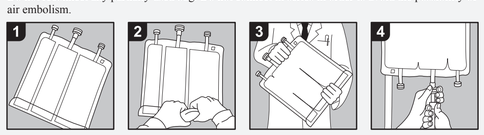
To mix the chambers:
- Ensure that the product is at room temperature when breaking the nonpermanent seals.
- Manually roll the bag onto itself, starting at the top of the bag (hanger end). *(Picture 1)* The nonpermanent seals will disappear from the side near the inlets. Continue to roll the bag until the seals are open along approximately half of their length. *(Picture 2)*
- Mix by inverting the bag at least 3 times. *(Picture 3)*
- 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. (see "Addition" sub-section)

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. (*Picture 4*)

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.



Addition
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 PERI 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 PERI
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 (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)	2 vials[b]/bag
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 9.2 mmol/L
Selenium	7.6 µmol/L
Zinc	0.31 mmol/L

[a] Volume of vial: 10mL concentrate solution
[b] Volume of vial: of 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 PERI 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, especially for an administration via a peripheral vein.

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