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Directions for Use

B. Braun Medical AG, Switzerland

Nutriflex® peri

Composition
Amounts of active ingredients in both the 1000 ml and 2000 ml sizes of the product before and after mixing of the two chambers are given below.

	Before Mixing		After Mixing	Before Mixing		After Mixing
Composition	**Lower Compartment 600 ml**	**Upper Compartment 400 ml**	**1000 ml**	**Lower Compartment 1200 ml**	**Upper Compartment 800 ml**	**2000 ml**
Isoleucine		2.34 g	2.34 g		4.68 g	4.68 g
Leucine		3.13 g	3.13 g		6.26 g	6.26 g
Lysine Hydrochloride		2.84 g	2.84 g		5.68 g	5.68 g
≙ Lysine		(2.27 g)	(2.27 g)		(4.54 g)	(4.54 g)
Methionine		1.96 g	1.96 g		3.92 g	3.92 g
Phenylalanine		3.51 g	3.51 g		7.02 g	7.02 g
Threonine		1.82 g	1.82 g		3.64 g	3.64 g
Tryptophan		0.57 g	0.57 g		1.14 g	1.14 g
Valine		2.60 g	2.60 g		5.20 g	5.20 g
Arginine Monoglutamate		4.98 g	4.98 g		9.96 g	9.96 g
≙ Arginine		(2.70 g)	(2.70 g)		(5.40 g)	(5.40 g)
≙ Glutamic Acid		(2.28 g)	(2.28 g)		(4.56 g)	(4.56 g)
Histidine Hydrochloride Monohydrate		1.69 g	1.69 g		3.38 g	3.38 g
≙ Histidine		(1.25 g)	(1.25 g)		(2.50 g)	(2.50 g)
Alanine		4.85 g	4.85 g		9.70 g	9.70 g
Aspartic Acid		1.50 g	1.50 g		3.00 g	3.00 g
Glutamic Acid		1.22 g	1.22 g		2.44 g	2.44 g
Glycine		1.65 g	1.65 g		3.30 g	3.30 g
Proline		3.40 g	3.40 g		6.80 g	6.80 g
Serine		3.00 g	3.00 g		6.00 g	6.00 g
Magnesium Acetate Tetrahydrate		0.86 g	0.86 g		1.72 g	1.72 g
Sodium Acetate Trihydrate		1.56 g	1.56 g		3.12 g	3.12 g
Potassium Dihydrogen Phosphate		0.78 g	0.78 g		1.56 g	1.56 g
Potassium Hydroxide		0.52 g	0.52 g		1.04 g	1.04 g
Sodium Hydroxide		0.50 g	0.50 g		1.00 g	1.00 g
Glucose Monohydrate	88.0 g		88.0 g	176.0 g		176.0 g
≙ Anhydrous Glucose	(80.0 g)		(80.0 g)	(160.0 g)		(160.0 g)
Sodium Chloride	0.17 g		0.17 g	0.34 g		0.34 g
Calcium Chloride Dihydrate	0.37 g		0.37 g	0.74 g		0.74 g
Electrolytes:						
Sodium	3.0 mmol	24.0 mmol	27.0 mmol	6.0 mmol	48.0 mmol	54.0 mmol
Potassium		15.0 mmol	15.0 mmol		30.0 mmol	30.0 mmol
Calcium	2.5 mmol		2.5 mmol	5.0 mmol		5.0 mmol
Magnesium		4.0 mmol	4.0 mmol		8.0 mmol	8.0 mmol
Chloride	8.0 mmol	23.6 mmol	31.6 mmol	16.0 mmol	47.2 mmol	63.2 mmol
Dihydrogen phosphate		5.7 mmol	5.7 mmol		11.4 mmol	11.4 mmol
Acetate		19.5 mmol	19.5 mmol		39.0 mmol	39.0 mmol
Total Amino Acids		40 g	40 g		80 g	80 g
Nitrogen		5.7 g	5.7 g		11.4 g	11.4 g
Non-protein energy kJ (kcal)	1340 (320)		1340 (320)	2680 (640)		2680 (640)
kJ (kcal), total	1340 (320)	670 (160)	2010 (480)	2680 (640)	1340 (320)	4020 (960)
Osmolarity (mOsm/l)			900			900

Excipients
Citric acid and Water for Injections.

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Pharmaceutical form
Solution for infusion.

Indications
Supply of the daily requirements of energy, amino acids, electrolytes and fluids during parenteral nutrition for patients with mild to moderately severe catabolism when oral or enteral nutrition is impossible, insufficient or contraindicated.

Contraindications
This product must not be administered in the following conditions
- disturbances of amino acid metabolism,
- hyperkalaemia; hyponatraemia,
- unstable metabolism (e.g.unstable diabetes mellitus),
- coma of unknown origin,
- hyperglycaemia not responding to insulin doses of up to 6 units insulin/hour,
- acidosis,
- severe hepatic insufficiency,
- severe renal insufficiency,
- known hypersensivity to any of the ingredients.

On account of its composition the product should not be used for neonates, infants and children under 2 years of age.

General contra-indications to parenteral nutrition are:
- unstable circulatory status with vital threat (states of collapse and shock),
- inadequate cellular oxygen supply,
- states of hyperhydration,
- disturbances of the electrolyte and fluid balance,
- acute pulmonary oedema, decompensated cardiac insufficiency

Special warnings and precautions for use
Caution should be exercised in cases of increased serum osmolarity
As for all large-volume infusion solutions Nutriflex® peri should be administered with caution to patients with impaired cardiac or renal function. Disturbances of the fluid, electrolyte or acid-base balance, e.g. hyperhydration, hyperkalaemia, acidosis, should be corrected before the start of infusion. Too rapid infusion can lead to fluid overload with pathological serum electrolyte concentrations, hyperhydration and pulmonary oedema.
As with all solutions containing carbohydrates the administration of Nutriflex® peri can lead to hyperglycaemia. The blood glucose level should be monitored. If there is hyperglycaemia the rate of infusion should be reduced or insulin should be administered.
Intravenous infusion of amino acids is accompanied by increased urinary excretion of the trace elements, especially copper and, in particular, zinc. This should be considered in the dosing of trace elements, especially during long-term intravenous nutrition.
Nutriflex® peri should not be given simultaneously with blood in the same infusion set due to the risk of pseudoagglutination.
Moreover controls of the serum ionogramme, the water balance, the acid-base balance and – during long-term administration - of blood cell counts, coagulation status and hepatic function are necessary.
Substitution of additional energy in form of lipids, essential fatty acids, electrolytes, vitamins and trace elements may be necessary as required.
As with all intravenous solutions strict aseptic precautions are necessary for the infusion of Nutriflex® peri.
Nutriflex® peri is a preparation of complex composition. If the product is mixed with other solutions or emulsions, compatibility must be ensured.
As Nutriflex® peri can be administered peripherally the state of the veins should be taken into account. It is recommended to change the vein regularly.

Interactions
None known.

Pregnancy and lactation
Preclinical studies have not been performed with Nutriflex® peri. The prescriber should consider the benefit / risk relationship before administering Nutriflex® peri to pregnant women.
Breast-feeding is not recommended if women need parenteral nutrition in that time.

Dosage
The dosage is adapted to the patients' individual requirements.
The maximum daily dose amounts to 40 ml/kg body weight, corresponding to
- 1.6 g amino acids /kg body weight per day
- 3.2 g glucose /kg body weight per day

It is recommended that Nutriflex® peri be administered continuously.

The maximum rate of infusion is 2.0 ml/kg body weight per hour, corresponding to
- 0.08 g amino acids /kg body weight per hour
- 0.16 g glucose/kg body weight per hour.

For a patient weighing 70 kg this corresponds to an infusion rate of 140 ml per hour. The amount of amino acid administered is then 5.6 g/hour and of glucose 11.2 g/hour.
An individual adjustment of the dosage is necessary in liver insufficiency.

Duration of use
The duration of treatment for the indications stated should not exceed 7 days.

Method of administration
For intravenous infusion. Especially qualified for infusion in peripheral veins

Instructions for use/handling
Immediately before use the internal peal seam between the two compartments must be opened allowing the respective contents to be aseptically mixed.

Remove the bag from its protective pack and proceed as follows :
- open out the bag and lay on a solid surface
- open the peel seal by using pressure with both hands
- briefly mix the contents of the bag together.

After infusion, any remaining solution should never be stored for later use. Only completely clear solutions from undamaged containers are to be used.
Conventional aseptic precautions during the admixing of solutions or fat emulsions to Nutriflex® peri must be strictly observed. Fat emulsions can be easily admixed by means of a special transfer set.

Overdose
Overdose of Nutriflex® peri is not to be expected on proper administration.

Symptoms of fluid and electrolyte overdose
Hypertonic hyperhydration, electrolyte imbalance and pulmonary oedema.

Symptoms of amino acid overdose:
Renal amino acid losses with consecutive amino acid imbalances, sickness, vomiting and shivering.

Symptoms of glucose overdose:
Hyperglycaemia, glucosuria, dehydration, hyperosmolality, hyperglycaemic and hyperosmolar coma.

Treatment:
Immediate cessation of infusion is indicated for overdose. Further therapeutic measures depend on the particular symptoms and their severity. When infusion is recommenced after the symptoms have declined it is recommended that the infusion rate be raised gradually with monitoring at frequent intervals

Undesirable effects
Undesirable effects with the components of Nutriflex® peri are rare. Those that do occur are usually reversible and regress when therapy is discontinued. Nausea or vomiting may occasionally occur. In the event of a forced infusion an osmotic diuresis might occur as a result of the high osmolarity.
If these side effects occur the infusion should be discontinued or, if appropriate, the infusion should be continued at a lower dose level.

Note:
Patients are advised to inform their doctor or pharmacist if they notice any adverse effect not mentioned in this leaflet.

Expiry date
The product must not be used after the expiry date printed on the container.

Instructions for storage / use / handling
Do not store above 25 °C
To protected from light, keep containers in the outer carton.
Ideally after mixing the two solutions, Nutriflex® peri should be administered immediately but in special circumstances it can be stored for up to 7 days at room temperature and up to 14 days if stored in a refrigerator (including administration time).

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