NAME OF THE MEDICINAL PRODUCT

Nutriflex peri Solution for Infusion

COMPOSITION

Amounts of active substances in both the 1000 ml and 2000 ml sizes of the product are given below.

Composition	**in 1000 ml**	**in 2000 ml**
	from the upper chamber (400 ml)	**from the upper chamber (800 ml)**
Isoleucine	2.34 g	4.68 g
Leucine	3.13 g	6.26 g
Lysine hydrochloride (equivalent to lysine:)	2.84 g (2.27 g)	5.68 g (4.54 g)
Methionine	1.96 g	3.92 g
Phenylalanine	3.51 g	7.02 g
Threonine	1.82 g	3.64 g
Tryptophan	0.57 g	1.14 g
Valine	2.60 g	5.20 g
Arginine monoglutamate (equivalent to arginine:) (equivalent to glutamic acid:)	4.98 g (2.70 g) (2.28 g)	9.96 g (5.40 g) (4.56 g)
Histidine hydrochloride monohydrate (equivalent to histidine:)	1.69 g (1.25 g)	3.38 g (2.50 g)
Alanine	4.85 g	9.70 g
Aspartic acid	1.50 g	3.00 g
Glutamic acid	1.22 g	2.44 g
Glycine	1.65 g	3.30 g
Proline	3.40 g	6.80 g
Serine	3.00 g	6.00 g
Magnesium acetate tetrahydrate	0.86 g	1.72 g
Sodium acetate trihydrate	1.56 g	3.12 g
Potassium dihydrogen phosphate	0.78 g	1.56 g
Potassium hydroxide	0.52 g	1.04 g
Sodium hydroxide	0.50 g	1.00 g
	from the lower chamber (600 ml)	**from the lower chamber (1200 ml)**
Glucose monohydrate	88.0 g	176.0 g

(equivalent to glucose:)	(80.0 g)	(160.0 g)
Sodium chloride	0.17 g	0.34 g
Calcium chloride dihydrate	0.37 g	0.74 g

Electrolytes:	**in 1000 ml**	**in 2000 ml**
Sodium	27.0 mmol	54.0 mmol
Potassium	15.0 mmol	30.0 mmol
Magnesium	4.0 mmol	8.0 mmol
Phosphate	5.7 mmol	11.4 mmol
Acetate	19.5 mmol	39.0 mmol
Chloride	31.6 mmol	63.2 mmol
Calcium	2.5 mmol	5.0 mmol
	in 1000 ml	**in 2000 ml**
Amino acid content	40 g	80 g
Nitrogen content	5.7 g	11.4 g
Carbohydrate content	80 g	160 g

	in 1000 ml	**in 2000 ml**
Energy in the form of amino acids [kJ (kcal)]	669 (160)	1339 (320)
Energy in the form of carbohydrates [kJ (kcal)]	1339 (320)	2678 (640)
Total energy [kJ (kcal)]	2008 (480)	4017 (960)

Excipients: Citric acid monohydrate, water for injection.

THERAPEUTIC INDICATIONS

Supply of amino acids, glucose, electrolytes and fluid in the parenteral nutrition of patients in states of mild to moderate catabolism when oral or enteral nutrition is impossible, insufficient or contraindicated. Nutriflex peri is indicated in adults and children aged 2 to 17 years.

CONTRAINDICATIONS

Hypersensitivity to the active substance(s) or to any of the excipients.
Inborn errors of amino acid metabolism, hyperglycaemia not responding to insulin doses of up to 6 units insulin/hour, intracranial or intraspinal haemorrhage, acidosis, severe hepatic insufficiency, severe renal insufficiency in absence of renal replacement therapy.

On account of its composition, Nutriflex peri must not be used in newborn infants, infants and toddlers < 2 years of age.

General contraindications to parenteral nutrition include unstable circulatory status with vital threat (e.g. states of collapse, shock, fluid overload, pulmonary oedema etc.), acute myocardial infarction and stroke, unstable metabolic condition (e.g. coma of unknown origin, hypoxia, decompensated diabetes mellitus etc.).

UNDESIRABLE EFFECTS

Summary of the safety profile
Undesirable systemic effects with the components of Nutriflex peri are rare (≥ 1/10 000 to < 1/1000) and usually related to inadequate dosage and/or infusion rate. Those that do occur are usually reversible and regress when therapy is discontinued.

Undesirable effects are listed according to their frequencies as follows:

Common: (≥ 1/100 to < 1/10)
Rare: (≥ 1/10 000 to < 1/1000)

Gastrointestinal disorders
Rare: Nausea, vomiting, decreased appetite

General disorders and administration site conditions
Common: Vein irritation, phlebitis, thrombophlebitis

Information on particular undesirable effects
If nausea, vomiting or decreased appetite occur, the infusion should be discontinued or, if appropriate, the infusion should be continued at a lower dose level.

If signs of vein wall irritation, phlebitis or thrombophlebitis occur, change of the infusion site should be considered.

WARNINGS

Keep out of the sight and reach of children.

NOTE

Prescription only
Not all products are registered and approved for sale in all countries or regions. Indications of use may also vary by country and region. Please contact your country representative for product availability and information.

B. Braun Melsungen AG, 34209 Melsungen, Germany, 05/2017

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