

**NAME OF THE MEDICINAL PRODUCT**

Nutriflex special Solution for Infusion

**COMPOSITION**

Amounts of active substances in both the 1000 ml and 1500 ml sizes of the product are given below.

<b>Composition</b>	<b>in 1000 ml</b>	<b>in 1500 ml</b>
	<b>from the upper chamber (500 ml)</b>	<b>from the upper chamber (750 ml)</b>
Isoleucine	4.11 g	6.17 g
Leucine	5.48 g	8.22 g
Lysine hydrochloride (equivalent to lysine:)	4.97 g (3.98 g)	7.46 g (5.97 g)
Methionine	3.42 g	5.13 g
Phenylalanine	6.15 g	9.23 g
Threonine	3.18 g	4.77 g
Tryptophan	1.00 g	1.50 g
Valine	4.54 g	6.81 g
Arginine monoglutamate (equivalent to arginine:) (equivalent to glutamic acid:)	8.72 g (4.73 g) (3.99 g)	13.08 g (7.10 g) (5.99 g)
Histidine hydrochloride monohydrate (equivalent to histidine:)	2.96 g (2.19 g)	4.44 g (3.29 g)
Alanine	8.49 g	12.74 g
Aspartic acid	2.63 g	3.95 g
Glutamic acid	2.15 g	3.23 g
Glycine	2.89 g	4.34 g
Proline	5.95 g	8.93 g
Serine	5.25 g	7.88 g
Magnesium acetate tetrahydrate	1.08 g	1.62 g
Sodium acetate trihydrate	1.63 g	2.45 g
Potassium dihydrogen phosphate	2.00 g	3.00 g
Potassium hydroxide	0.62 g	0.93 g
Sodium hydroxide	1.14 g	1.71 g
	<b>from the lower chamber (500 ml)</b>	<b>from the lower chamber (750 ml)</b>
Glucose monohydrate	264.0 g	396.0 g

(equivalent to glucose:)	(240.0 g)	(360.0 g)
Calcium chloride dihydrate	0.60 g	0.90 g

<b>Electrolytes:</b>	<b>in 1000 ml</b>	<b>in 1500 ml</b>
Sodium	40.5 mmol	60.8 mmol
Potassium	25.7 mmol	38.6 mmol
Magnesium	5.0 mmol	7.5 mmol
Phosphate	14.7 mmol	22.1 mmol
Acetate	22.0 mmol	33.0 mmol
Chloride	49.5 mmol	74.3 mmol
Calcium	4.1 mmol	6.2 mmol
	<b>in 1000 ml</b>	<b>in 1500 ml</b>
Amino acid content	70 g	105 g
Nitrogen content	10 g	15 g
Carbohydrate content	240 g	360 g
	<b>in 1000 ml</b>	<b>in 1500 ml</b>
Energy in the form of amino acids [kJ (kcal)]	1172 (280)	1757 (420)
Energy in the form of carbohydrates [kJ (kcal)]	4017 (960)	6025 (1440)
Total energy [kJ (kcal)]	5198 (1240)	7782 (1860)

*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 moderate to severe catabolism when oral or enteral nutrition is impossible, insufficient or contraindicated.

Nutriflex special 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 special 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 special are rare ( $\geq 1/10\ 000$  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:

Rare: ( $\geq 1/10\ 000$  to  $< 1/1000$ )

### ***Gastrointestinal disorders***

Rare: Nausea, vomiting, decreased appetite

### ***Renal and urinary disorders***

Rare: Polyuria

### 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.

## 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.

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