

Aminoplasmal®

Composition

Each 1000 ml contains:

	Aminoplasmal [†]					
	-5 % E	-10 %	-10 % E	-12.5 %E	-15 % E	15 %
Isoleucine	2.55 g	5.10 g	5.10 g	6.38 g	5.85 g	5.85 g
Leucine	4.45 g	8.90 g	8.90 g	11.13 g	11.40 g	11.40 g
Lysine Hydrochloride	3.50 g	7.00 g	7.00 g	8.75 g	6.60 g	-
(Δ Lysine)	(2.80 g)	(5.60 g)	(5.60 g)	(7.00 g)	(7.95 g)	(7.95 g)
Methionine	1.90 g	3.80 g	3.80 g	4.75 g	5.70 g	5.70 g
Phenylalanine	2.55 g	5.10 g	5.10 g	6.38 g	5.70 g	5.70 g
Threonine	2.05 g	4.10 g	4.10 g	5.13 g	5.40 g	5.40 g
Tryptophan	0.90 g	1.80 g	1.80 g	2.25 g	2.10 g	2.10 g
Valine	2.40 g	4.80 g	4.80 g	6.00 g	7.20 g	7.20 g
Arginine	4.60 g	9.20 g	9.20 g	11.50 g	16.05 g	16.05 g
Histidine	2.60 g	5.20 g	5.20 g	6.00 g	5.25 g	5.25 g
Glycine	3.95 g	7.90 g	7.90 g	9.88 g	19.20 g	19.20 g
Alanine	6.85 g	13.70 g	13.70 g	17.13 g	22.35 g	22.35 g
Proline	4.45 g	8.90 g	8.90 g	11.13 g	7.35 g	7.35 g
Aspartic acid	0.65 g	1.30 g	1.30 g	1.63 g	7.95 g	7.95 g
Asparagine · H ₂ O	1.86 g	3.72 g	3.72 g	4.65 g	-	-
(Δ Asparagine)	(1.64 g)	(3.27 g)	(3.27 g)	(4.09 g)	-	-
Acetylcysteine	0.34 g	0.68 g	0.68 g	0.85 g	0.50 g	0.50 g
(Δ Cysteine)	(0.25 g)	(0.50 g)	(0.50 g)	(0.63 g)	(0.37 g)	(0.37 g)
Glutamic acid	2.30 g	4.60 g	4.60 g	5.75 g	16.20 g	16.20 g
Ornithine Hydrochloride	1.60 g	3.20 g	3.20 g	4.00 g	-	-
(Ornithine)	(1.25 g)	(2.51 g)	(2.51 g)	(3.14 g)	-	-
Serine	1.20 g	2.40 g	2.40 g	3.00 g	3.00 g	3.00 g
Tyrosine	0.30 g	0.30 g	0.30 g	0.30 g	0.50 g	0.50 g
Acetyltyrosine	0.43 g	1.23 g	1.23 g	1.64 g	-	-
(Δ Tyrosine)	(0.35 g)	(1.00 g)	(1.00 g)	(1.33 g)	-	-
Sodium acetate · 3H ₂ O	3.95 g	-	3.95 g	3.95 g	-	-
Potassium acetate	2.45 g	-	2.45 g	2.45 g	2.95 g	-
Magnesium acetate · 4H ₂ O	0.56 g	-	0.56 g	0.56 g	0.56 g	-
Sodium dihydrogen phosphate · 2H ₂ O	1.40 g	-	1.40 g	1.40 g	1.40 g	-
Sodium hydroxide	0.20 g	-	0.20 g	0.20 g	1.40 g	-
L-malic acid	1.01 g	-	1.01 g	1.01 g	-	-
Water for injections to	1,000 ml	1,000 ml	1,000 ml	1,000 ml	1,000 ml	1,000 ml

Composition

(per 1000 ml)

	Aminoplasmal [†]					
	-5% E	-10%	-10% E	-12.5% E	-15% E	15%
Electrolytes (mmol/l)						
Sodium		43	-	43	43	50
Potassium		25	-	25	25	30
Magnesium		2.6	-	2.6	2.6	2.6
Acetate		59	-	59	59	35
Chloride		29	57	57	72	36
Dihydrogen phosphate		9.0	-	9.0	9.0	9.0
L-Malate		7.5	-	7.5	7.5	-
Total amino acids (g/l)	50	100	100	125	150	150
Total nitrogen (g/l)	8	16	16	20	24	24
Caloric value (kJ/l)	835	1675	1675	2095	2510	251
(kcal/l)	200	400	400	500	600	600
Osmolarity (mOsm/l)	590	885	1030	1250	1480	1290

Indication

Parenteral nutrition.

Contraindications

Disturbances of amino acid metabolism, acidosis, overhydration.
Hyperkalaemia (Aminoplasmal -5% E, -10% E, -12.5% E, -15% E),
Hypokalaemia (Aminoplasmal 10%, 15%).

Precautions

Regular monitoring should include water balance, serum ionogram, blood glucose levels and serum osmolality.
Individual regimens must be established in patients with hepatic and renal failure. Aminoplasmal has to be combined with appropriate non-protein calories (carbohydrate solutions, fat emulsions). Too rapid infusion may lead to symptoms of intolerance, renal amino acid losses and imbalances.
Side effects
Not anticipated if contraindications, dosage guidelines and precautions are respected.

Subject to sales by pharmacists only.

B. Braun Melsungen AG
D-34209 Melsungen

Aminoplasma® Hepa 10%

Composition

Each 1000 ml contains:

Isoleucine	8.80 g
Leucine	13.60 g
Lysine Acetate (equivalent to Lysine 7.51 g)	10.60 g
Methionine	1.20 g
Phenylalanine	1.60 g
Threonine	4.60 g
Tryptophan	1.50 g
Valine	10.60 g
Arginine	8.80 g
Histidine	4.70 g
Glycine	6.30 g
Alanine	8.30 g
Proline	7.10 g
Aspartic Acid	2.50 g
Asparagine · H ₂ O (equivalent to Asparagine 0.48 g)	0.55 g
Acetylcysteine (equivalent to Cysteine 0.59 g)	0.80 g
Glutamic Acid	5.70 g
Ornithine Hydrochloride (equivalent to Ornithine 1.35 g)	1.66 g
Serine	3.70 g
Acetyltyrosine (equivalent to Tyrosine 0.67 g)	0.86 g
Water for Injections	to 1,000 ml
Total amino acids	100 g/l
Total nitrogen	15.3 g/l
Caloric value:	1,675 kJ/l 400 kcal/l
Osmolarity:	875 mOsm/l
Electrolytes:	
Acetate	51 mmol/l
Chloride	10 mmol/l

Indications

Prophylaxis and therapy of hepatic encephalopathy.

Parenteral nutrition in liver diseases when hepatic encephalopathy is either imminent or already manifest. Normalisation of amino acid imbalances arising from severe liver diseases.

Contraindications

Disturbances of amino acid metabolism of other than hepatic origin, acidosis, overhydration, hypokalaemia.

Precautions

Clinical supervision should include regular checks of fluid balance and serum electrolytes. Carbohydrates and electrolytes are to be supplemented as required. Caution is to be exercised in patients with hyponatraemia or with increased serum osmolarity.

Unusually rapid infusion rates may produce signs of intolerance and renal amino acid losses resulting in amino acid imbalances.

In cases of concurrent renal insufficiency the dosage of amino acids has to be adapted to the serum urea and creatinine values. Amino acid therapy is not a substitute for established therapeutic measures, such as purging, administration of lactulose and/or gut sterilising antibiotics, in the treatment of hepatic encephalopathy.

It is not recommended that any additives be incorporated into Aminoplasma® Hepa-10% solution, but should preferably be given in standard carbohydrate or electrolyte solutions. However, if admixture with Aminoplasma® Hepa-10% is essential, then the compatibility of the additive must be checked before administration.

Side-effects

Provided contraindications, dosage recommendations and precautions are observed, side-effects are not anticipated.

Subject to sales by pharmacists only.

B. Braun Melsungen AG
D-34209 Melsungen

Glucose Intravenous Infusion

Composition:

Each 1000 ml solution contains:

		Glucose				
		10%	20%	40%	50%	70%
Glucose	(g)	100	200	400	500	700
As glucose monohydrate	(g)	110	220	440	550	770
Carbohydrate contents	(g)	100	200	400	500	700
Caloric value	(kJ/ kcal)	1675/ 400	3350/ 800	6700/ 1600	8375/ 2000	11725/ 2800
Theor. Osmolarity	(mOsm/l)	555	1100	2220	2770	3880

Indications

- Energy supply by means of glucose
- Carbohydrate component in parenteral nutrition
- Therapy of hypoglycaemia

Contraindications

- Elevated blood sugar concentration (hyperglycaemia)
- Decreased blood potassium concentration (hypokalaemia)
- High concentration of acid substances in blood (acidosis)
- Hyperhydration
- Simultaneous sodium and water deficiency (hypotonic dehydration)

Special warnings and precautions for use

This solution should only be administered with caution to patients with increased serum osmolarity. Patient monitoring should include regular checks of the blood glucose level, depending on the prevailing metabolic condition and the administered dose. Patient monitoring should also include regular checks of the water balance, the serum electrolyte concentrations – in particular serum potassium – and the acid-base balance.

Glucose Infusions should not be administered through the same infusion equipment, simultaneously with, before, or after administration of blood, because of the possibility of pseudo-agglutination.

Subject to sale by pharmacists only.

B. Braun Melsungen AG
D-34209 Melsungen

Lipofundin® N

Composition

1000 ml emulsion contains:

	Lipofundin® N 10%	Lipofundin® N 20%
Soya oil	100.0 g	200.0 g
Glycerol	25.0 g	25.0 g
Egg Lecithin	8.0 g	12 g
Sodium Oleate, α - Tocopherol, Water for Injections		
Megajoules/l (approx.):	4.5 (1072 kcal)	8.4 (2008 kcal)
Milliosmols/l (approx.):	345	380
pH:	6.5–8.8	6.5–8.5

Indications

Lipofundin® N is indicated as a source of calories and essential fatty acids for patients requiring parenteral nutrition.

Contraindications

The administration of Lipofundin® N is contraindicated in patients demonstrating disturbances in normal fat metabolism such as pathologic hyperlipaemia, lipoid nephrosis, or acute pancreatitis if accompanied by hyperlipaemia. It is further contraindicated in patients with ketoacidosis or hypoxia, in thromboembolism and in acute shock states.

Precautions for use

Caution should be exercised in administering intravenous fat emulsions in patients with metabolic acido-

sis, severe liver damage, pulmonary disease, sepsis, diseases of the reticuloendothelial system, anaemia or blood coagulation disorders or when there is danger of fat embolism.

Administration of Lipofundin® N should be accompanied by simultaneous carbohydrate infusions making up to 40% (at least) of the total calorie intake. When Lipofundin® N is administered, the patient's capacity to eliminate the infused fat from the circulation must be monitored. The lipaemia must clear between daily infusions. Especially where fat emulsions are administered for extended periods of time, the patient's haemogram, blood coagulation, liver function and platelet count should be closely monitored.

Use in pregnancy and lactation

The safety of Lipofundin® N during pregnancy and lactation has not been assessed, but its use during these periods is not considered to constitute a hazard. Nevertheless, medicines should not be used in pregnancy, especially during the first trimester, unless the expected benefit is thought to outweigh any possible risk to the foetus.

Special warnings

The too rapid infusion of fat emulsions can cause fluid and/or fat overloading resulting in dilution of serum electrolyte concentrations, overhydration, congested states, pulmonary oedema, impaired pulmonary diffusion capacity. A too rapid infusion of Lipofundin® N can also cause hyperketonaemia and/or metabolic acidosis, especially when carbohydrates are not administered simultaneously.

Subject to sale by pharmacists only.

B. Braun Melsungen AG
D-34209 Melsungen

Lipofundin® MCT/LCT

Composition

1000 ml emulsion contain

	Lipofundin® MCT/LCT 10%	Lipofundin® MCT/LCT 20%
Soybean oil	50.0 g	100.0 g
Mediumchain Triglycerides	50.0 g	100.0 g
Glycerol	25.0 g	25.0 g
Egg yolk phospholipids*	8.0 g	12.0 g
Sodium Oleate, α -Tocopherol*, Water for injections		
Megajoules/l (approx.):	4.43 (1022 kcal)	7.99 (1908 kcal)
Milliosmols/l (approx.):	345	380
pH:	6.5-8.8	6.5-8.5

* The amount of egg yolk phospholipids and α -tocopherol can vary in some countries. Please refer to the country representative. Soybean oil is a refined natural product containing neutral triglycerides of predominantly unsaturated fatty acids. Medium-chain triglycerides are a mixture of neutral triglycerides of mainly caprylic (about 60%) and capric acid (about 40%).

Indications

Lipofundin® MCT/LCT is indicated as a source of calories and essential fatty acids for patients requiring parenteral nutrition.

Contraindications

The administration of Lipofundin® MCT/LCT is contraindicated in patients demonstrating disturbances in normal fat metabolism such as pathologic hyperlipaemia, lipoid nephrosis, or acute pancreatitis if accompanied by hyperlipaemia. It is further contraindicated in patients with ketoacidosis or hypoxia, in thromboembolism and in acute shock states.

Precautions for use

Caution should be exercised in administering intravenous fat emulsions in patients with metabolic acidosis, severe liver damage, pulmonary disease, sepsis, diseases of the reticuloendothelial system, anaemia or blood coagulation disorders or when there is danger of fat embolism. Administration of Lipofundin® MCT/LCT should be accompanied by simultaneous carbohydrate infusions making up to

40% (at least) of the total calorie intake.

When Lipofundin® MCT/LCT is administered, the patient's capacity to eliminate the infused fat from the circulation must be monitored. The lipaemia must clear between daily infusions. Especially where fat emulsions are administered for extended periods of time, the patient's haemogram, blood coagulation, liver function and platelet count should be closely monitored.

Paediatric patients: studies have shown the safety and effectiveness of Lipofundin® MCT/LCT as part of total parenteral nutrition in neonates and older children.

Lipofundin® MCT/LCT has been approved for usage in this patient population in some countries.

Registration procedures are currently pursued in other countries. As long as approval has not been obtained in a specific country it is up to the judgement of the responsible physician whether or not to use Lipofundin® MCT/LCT in this patient group.

Use in pregnancy and lactation

The safety of Lipofundin® MCT/LCT during pregnancy and lactation has not been assessed, but its use

during these periods is not considered to constitute a hazard. Nevertheless, medicines should not be used in pregnancy, especially during the first trimester, unless the expected benefit is thought to outweigh any possible risk to the foetus.

Special warnings

The too rapid infusion of fat emulsions can cause fluid and/or fat overloading resulting in dilution of serum electrolyte concentrations, overhydration, congested states, pulmonary oedema, impaired pulmonary diffusion capacity. A too rapid infusion of Lipofundin® MCT/LCT can also cause hyperketonaemia and/or metabolic acidosis, especially when carbohydrates are not administered simultaneously.

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B. Braun Melsungen AG
D-34209 Melsungen

Nutriflex®

Composition

Nutriflex® (mixed and ready for use 1000 ml)

Active ingredients

Nutriflex®	peri (40/80)	basal (32/125)	plus (48/150)	special (70/240)
L-isoleucine	2.34 g	1.88 g	2.82 g	4.11 g
L-leucine	3.13 g	2.50 g	3.76 g	5.48 g
L-lysine HCl (equivalent to L-lysine)	2.84 g 2.27 g	2.27 g 1.82 g	3.41 g 2.73 g	4.97 g 3.98 g
L-methionine	1.96 g	1.56 g	2.35 g	3.42 g
L-phenylalanine	3.51 g	2.81 g	4.21 g	6.15 g
L-threonine	1.82 g	1.45 g	2.18 g	3.18 g
L-tryptophan	0.57 g	0.46 g	0.68 g	1.00 g
L-valine	2.60 g	2.08 g	3.12 g	4.54 g
Arginine glutamate (equivalent to Arginine and to Glutamic acid)	4.98 g 2.70 g	3.98 g 2.16 g	5.98 g 3.24 g	8.72 g 4.73 g
L-histidine · HCl · H ₂ O (equivalent to Histidine)	2.28 g 1.69 g	1.82 g 1.35 g	2.74 g 2.03 g	3.99 g 2.96 g
L-alanine	1.25 g	1.00 g	1.50 g	2.19 g
L-aspartic acid	4.85 g	3.88 g	5.82 g	8.49 g
L-(+)-glutamic acid	1.50 g	1.20 g	1.80 g	2.63 g
Amino acetic acid	1.22 g	0.98 g	1.47 g	2.15 g
L-proline	1.65 g	1.32 g	1.98 g	2.89 g
L-serine	3.40 g	2.72 g	4.08 g	5.95 g
Glucose · H ₂ O (equivalent to anhydrous glucose)	3.00 g 88.00 g	2.40 g 137.50 g	3.60 g 165.00 g	5.25 g 264.00 g
Sodium chloride	80.00 g	125.00 g	150.00 g	240.00 g
Calcium chloride · 2H ₂ O	0.17 g	1.40 g	–	–
Magnesium acetate · 4H ₂ O	0.37 g	0.53 g	0.53 g	0.60 g
Sodium dihydrogen phosphate · 2H ₂ O	0.86 g	1.23 g	1.23 g	1.08 g
Potassium dihydrogen phosphate	–	–	3.12 g	–
Sodium acetate · 3H ₂ O	0.78 g	1.74 g	–	2.00 g
Potassium hydroxide	1.56 g	3.20 g	1.56 g	1.63 g
Sodium hydroxide	0.52 g	0.96 g	1.40 g	0.62 g
Water for injections to	0.50 g	0.10 g	0.23 g	1.14 g
	1000 ml	1000 ml	1000 ml	1000 ml

Nutriflex®	peri (40/80)	basal (32/125)	plus (48/150)	special (70/240)
Total amino acids (g/l)	40	32	48	70
Total nitrogen (g/l)	5.7	4.6	6.8	10.0
Total carbohydrates (g/l)	80	125	150	240
Total energy kJ/l (kcal/l)	2010 (480)	2640 (630)	3310 (790)	5190 (1240)
Non-protein energy kJ/l (kcal/l)	1340 (320)	2090 (500)	2510 (600)	4020 (960)
Osmolarity (mOsm/l)	900	1140	1400	2100

Electrolytes:	mmol	mmol	mmol	mmol
Na ⁺	27.0	49.9	37.2	40.5
K ⁺	15.0	30.0	25.0	25.7
Ca ⁺⁺	2.5	3.6	3.6	4.1
Mg ⁺⁺	4.0	5.7	5.7	5.0
Cl ⁻	31.6	50.0	35.5	49.5
H ₂ PO ₄ ⁻	5.7	12.8	20.0	14.7
Acetate	19.5	35.0	22.9	22.0

Indication

Parenteral nutrition.

Contraindications

Nutriflex® is contraindicated in cases of hyperglycaemia, disorders of amino acid metabolism, manifest congestive cardiac failure, untreated shock, overhydration, enhanced plasma potassium levels, acidosis. In hepatic or renal insufficiency the dosage is to be individually adjusted. Because of the specific composition of the nutrients the use of Nutriflex® in newborns, infants and children up to the 2nd year of life is not recommended.

Precautions

Serum ionogram, water balance, blood glucose levels and acid-base balance are to be monitored. Possible intolerance reactions (nausea, vomiting, chills) and renal loss of glucose and amino acids with subsequent amino acid imbalances are due to a too rapid infusion rate.

Adverse reactions

Adverse reactions are not to be expected, and besides have not been reported so far, if contraindications, dosage recommendations, warnings and precautions are observed.

Subject to sale by pharmacists only.

B. Braun Melsungen AG
D-34209 Melsungen

NuTRiflex® Lipid

Composition

NuTRiflex® Lipid (mixed and ready for use 1250 ml)

Active ingredients

	NuTRiflex® Lipid peri	NuTRiflex® Lipid plus	NuTRiflex® Lipid plus without electrolytes	NuTRiflex® Lipid special	NuTRiflex® Lipid special without electrolytes	NuTRiflex® Lipid peri	NuTRiflex® Lipid plus	NuTRiflex® Lipid plus without electrolytes	NuTRiflex® Lipid special	NuTRiflex® Lipid special without electrolytes	
Isoleucine	2.34 g	2.82 g	2.82 g	4.105 g	4.10 g	Sodium dihydrogen phosphate dihydrate	1.170 g	2.34 g	–	3.120 g	–
Leucine	3.13 g	3.76 g	3.76 g	5.48 g	5.48 g	Sodium hydroxide	0.800 g	0.976 g	–	1.464 g	–
Lysinehydrate	–	–	3.065 g	–	4.47 g	Sodium chloride	1.081 g	0.503 g	–	0.473 g	–
Δ Lysine	–	–	2.73 g	–	3.98 g	Sodium acetate trihydrate	0.544 g	0.277 g	–	0.313 g	–
Lysine hydrochloride	2.84 g	3.41 g	–	4.975 g	–	Potassium acetate	2.943 g	3.434 g	–	4.611 g	–
Δ Lysine	2.26 g	2.73 g	–	3.98 g	–	Magnesium acetate tetrahydrate	0.644 g	0.858 g	–	1.137 g	–
Methionine	1.96 g	2.35 g	2.35 g	3.42 g	3.42 g	Calcium chloride dihydrate	0.441 g	0.588 g	–	0.779 g	–
Phenylalanine	3.51 g	4.21 g	4.21 g	6.145 g	6.145 g	Zinc acetate dihydrate	6.6 mg	6.58 mg	–	8.78 mg	–
Threonine	1.82 g	2.18 g	2.18 g	3.175 g	3.175 g	Total amino acids	40 g	48 g	48 g	70 g	70 g
Tryptophan	0.57 g	0.68 g	0.68 g	1.00 g	1.00 g	Total nitrogen	5.7 g	6.8 g	6.8 g	10 g	10 g
Valine	2.60 g	3.12 g	3.12 g	4.505 g	4.505 g	Total glucose	80 g	150 g	150 g	180 g	180 g
Arginine	2.70 g	3.24 g	3.24 g	4.725 g	4.725 g	Total lipids	50 g	50 g	50 g	50 g	50 g
Histidine	1.69 g	2.03 g	–	2.96 g	–	Total energy (KJ/Kcal)	4000/955	5300/1265	5300/1265	6175/1475	6175/1475
hydrochloride monohydrate	–	–	–	–	–	Non-Protein energy (KJ/Kcal)	3330/795	4500/1075	4500/1075	5005/1195	5005/1195
Δ Histidine	1.25 g	1.50 g	1.50 g	2.19 g	2.19 g	Osmolality (mOsm/kg)	920	1540	1350	2090	1840
Alanine	4.85 g	5.82 g	5.82 g	8.49 g	8.49 g	Osmolality (theoret.) (mOsm/l)	840	1215	1055	1545	1330
Aspartic acid	1.50 g	1.80 g	1.80 g	2.625 g	2.625 g	Electrolytes:	mmol	mmol	–	mmol	–
Glutamic acid	3.50 g	4.21 g	4.21 g	6.135 g	6.135 g	Sodium	50	50	–	67	–
Glycine	1.65 g	1.98 g	1.98 g	2.89 g	2.89 g	Potassium	30	35	–	47	–
(Δ aminoacetic acid)	–	–	–	–	–	Calcium	3.0	4.0	–	5.3	–
Proline	3.40 g	4.08 g	4.08 g	5.95 g	5.95 g	Magnesium	3.0	4.0	–	5.3	–
Serine	3.00 g	3.60 g	3.60 g	5.25 g	5.25 g	Zinc	0.03	0.03	–	0.04	–
Glucose monohydrate	88.0 g	165.0 g	165.0 g	198.0 g	198.0 g	Chloride	48	45	–	60	–
Δ Anhydrous glucose	80.0 g	150.0 g	150.0 g	180.0 g	180.0 g	Phosphate	7.5	15	–	20	–
Soya bean oil	25.0 g	25.0 g	25.0 g	25.0 g	25.0 g	Acetate	40	45	–	60	–
Medium chain triglycerides	25.0 g	25.0 g	25.0 g	25.0 g	25.0 g						

Indications

When oral or enteral feeding is not possible, insufficient or contraindicated.

Contraindications

Acute shock, acute phase of myocardial and cerebral infarction, severe disorders of blood coagulation, acute thrombo-embolism or fat embolism, irreversible liver damage, intrahepatic cholestasis, severe uraemia when dialysis facilities are not available, disorders of lipid metabolism such as pathological hyperlipaemia and conditions associated with triglyceride accumulation during parenteral nutrition, inborn errors of amino acid metabolism, untreated or complicated diabetes mellitus, especially in the presence of coma related to keto-acidosis or diabetic precoma.

These infusions should not be given to neonates and infants up to the age of 24 months.

Precautions

Should be administered with caution to patients with cardiac or renal dysfunction. Disorders of the fluid, electrolyte, and acid-base balance, e. g., overhydration, hyperkalaemia, acidosis, should be corrected before administration. Too rapid infusion can cause fluid overloading resulting in overhydration, congested states, pulmonary oedema, impaired pulmonary diffusion capacity.

Give with caution in conditions of impaired lipid metabolism as in renal insufficiency, diabetes mellitus, pancreatitis, impaired liver function, hypothyroidism (if hypertriglyceridaemic), sepsis and in conditions of altered amino acid metabolism.

As with other solutions containing glucose, administration of NuTRiflex® Lipid formulations may lead to hyperglycaemia. Blood glucose levels should be monitored and the rate of infusion adjusted or insulin should be administered if hyperglycaemia occurs.

The patient's capacity to eliminate the infused fat from the circulation should be monitored. Especially where the product is administered for extended periods of time, the patient's haemogram, blood coagulation, liver function, and platelet count should be regularly monitored.

In patients suspected to have disorders of fat metabolism, fasting lipaemia should be excluded. In the case of fasting hypertriglyceridaemia the administration of fat is contraindicated. Likewise, hypertriglyceridaemia 12 hours after fat infusion indicates disorders of fat metabolism.

Fluid, electrolyte, and acid-base balance should be monitored.

As with all parenteral solutions administered through a peripheral/central venous catheter, strict aseptic precautions should be taken. Care should be taken to avoid complications of catheterisation including air embolism and venous thrombosis.

Undesirable effects

Undesirable effects related to the components of NuTRiflex® Lipid peri, NuTRiflex® Lipid plus, NuTRiflex® Lipid plus without electrolytes, NuTRiflex® Lipid special and NuTRiflex® Lipid special without electrolytes are rare. Those that do occur are usually reversible and subside 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 osmolality.

During infusion in very rare cases the amino acids might cause hyperazotaemia and acidosis.

Immediate (acute) reactions related to the lipid are dyspnoea, cyanosis, allergic reactions, hyperlipaemia, hypercoagulability of the blood, nausea, vomiting, headache, flushing, hyperthermia, sweating, chills, sleepiness, chest and back pain. The infusion should be stopped in these cases. The infusion can be resumed after the disappearance of the symptoms and/or the elevated serum triglyceride levels with reduced dose and/or reduced infusion rate. Close monitoring of the patient's general condition and his/her plasma triglyceride levels is recommended.

Subject to medical prescription.

B. Braun Melsungen AG
D-34209 Melsungen

Tracutil®

Composition

1 ampoule of 10 ml contains

Active ingredients:

Iron (II) chlorid · 4 H ₂ O (equivalent to 35.0 µmol of iron)	6.958 mg
Zinc chloride, anhydrous (equivalent to 50.0 µmol of zinc)	6.815 mg
Manganese (II) chloride · 4 H ₂ O (equivalent to 10.0 µmol of manganese)	1.979 mg
Copper (II) chloride · 2 H ₂ O (equivalent to 12.0 µmol of copper)	2.046 mg
Chromium (III) chloride · 6 H ₂ O (equivalent to 0.2 µmol of chromium)	0.053 mg
Sodium molybdate · 2 H ₂ O (equivalent to 0.1 µmol of molybdenum)	0.0242 mg

Sodium selenite · 5 H ₂ O (equivalent to 0.3 µmol of selenium)	0.0789 mg
Sodium fluoride (equivalent to 30.0 µmol of fluoride)	1.260 mg
Potassium iodide (equivalent to 1.0 µmol of iodide)	0.166 mg

Excipients:

Hydrochloric acid, water for injections.

Therapeutic indications

Provision of basic trace element requirements during long-term parenteral nutrition in adult patients.

Contra-indications

Increased serum levels of the trace elements contained in Tracutil®. Tracutil® should not be administered to newborn infants, infants and children.

Notes:

Care is to be taken in cases of impaired liver or kidney function which requires a check of the serum concentrations and, where appropriate, reduction of the dose.

Caution is also necessary in case of Wilson's disease and disturbed iron storage (i.e. haemosiderosis or haemochromatosis) because copper and iron supplementation may cause an additional accumulation of these elements in such cases.

Special warnings and special precautions for use

In case of biliary tract disease administration of Tracutil® may lead to an accumulation of copper and manganese.

Chromium deficiency leads to a decrease in glucose tolerance, which improves again after chromium supplementation. For this reason,

patients suffering from insulin-dependent diabetes mellitus and chromium deficiency may require a reduction in the amount of insulin they receive during administration of Tracutil®.

Use in pregnancy and lactation:

There is no data available on administration during pregnancy or in the lactation period. The benefits must therefore be carefully weighed against the risks.

Undesirable effects

Individual cases of anaphylactic reactions to parenterally administered iron have been reported.

Dispensing classification

Subject to medical prescription.

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