173/12607453/0814

欣保富濾靜脈營養輸注液
NuTRIflex Lipid special

衛署藥輸字第024901號　　　　本藥限由醫師使用

成分

本品是三 連接密封袋包裝，各單袋之成份混合後即可使用之靜脈營養注射乳劑。各單袋之成份組成：

	625 ml	1250 ml	1875 ml	2500 ml
一 左上袋	**625 ml**	**1250 ml**	**1875 ml**	**2500 ml**
Glucose monohydrate	99.0 g	198.0 g	297.0 g	396.0 g
Equivalent to anhydrous glucose	90.0 g	180.0 g	270.0 g	360.0 g
Sodium dihydrogen phosphate dihydrate	1.56 g	3.120 g	4.680 g	6.240 g
Zinc acetate dihydrate	4.39 mg	8.78 mg	13.17 mg	17.56 mg
一 右上袋	**625 ml**	**1250 ml**	**1875 ml**	**2500 ml**
Soya-bean oil	12.5 g	25.0 g	37.5 g	50.0 g
Medium-chain triglycerides	12.5 g	25.0 g	37.5 g	50.0 g
一 下袋	**625 ml**	**1250 ml**	**1875 ml**	**2500 ml**
Isoleucine	2.06 g	4.11 g	6.16 g	8.21 g
Leucine	2.74 g	5.48 g	8.22 g	10.96 g
Lysine hydrochloride	2.49 g	4.98 g	7.46 g	9.95 g
equivalent to Lysine	1.99 g	3.98 g	5.96 g	7.95 g
Methionine	1.71 g	3.42 g	5.13 g	6.84 g
Phenylalanine	3.08 g	6.15 g	9.22 g	12.29 g
Threonine	1.59 g	3.18 g	4.76 g	6.35 g
Tryptophan	0.50 g	1.00 g	1.50 g	2.00 g
Valine	2.26 g	4.51 g	6.76 g	9.01 g
Arginine	2.37 g	4.73 g	7.09 g	9.45 g
Histidine hydrochloride monohydrate	1.48 g	2.96 g	4.44 g	5.92 g
equivalent to Histidine	1.10 g	2.19 g	3.29 g	4.38 g
Alanine	4.25 g	8.49 g	12.73 g	16.98 g
Aspartic acid	1.32 g	2.63 g	3.94 g	5.25 g
Glutamic acid	3.07 g	6.14 g	9.20 g	12.27 g
Glycine (aminoacetic acid)	1.45 g	2.89 g	4.33 g	5.78 g
Proline	2.98 g	5.95 g	8.93 g	11.90 g
Serine	2.63 g	5.25 g	7.88 g	10.50 g
Sodium hydroxide	0.732 g	1.464 g	2.196 g	2.928 g
Sodium chloride	0.237 g	0.473 g	0.710 g	0.946 g
Sodium acetate trihydrate	0.157 g	0.313 g	0.470 g	0.626 g
Potassium acetate	2.306 g	4.611 g	6.917 g	9.222 g
Magnesium acetate tetrahydrate	0.569 g	1.137 g	1.706 g	2.274 g
Calcium chloride dihydrate	0.390 g	0.779 g	1.168 g	1.558 g
	625 ml	**1250 ml**	**1875 ml**	**2500 ml**
Amino acid content [g]	35.9	71.8	107.7	143.6
Total nitrogen content [g]	5	10	15	20
Carbohydrate content [g]	90	180	270	360
Lipid content [g]	25	50	75	100
	625 ml	**1250 ml**	**1875 ml**	**2500 ml**
Energy in the form of lipid [KJ (kcal)]	995 (240)	1990 (475)	2985 (715)	3980 (950)
Energy in the form of carbohydrate [KJ (kcal)]	1510 (360)	3015 (720)	4520 (1080)	6030 (1440)
Energy in the form of amino acids [KJ (kcal)]	585 (140)	1170 (280)	1755 (420)	2340 (560)
Non-protein energy [KJ (kcal)]	2505 (600)	5005 (1195)	7510 (1795)	10010 (2390)
Total energy [KJ (kcal)]	3090 (740)	6176 (1475)	9265 (2215)	12350 (2950)
Osmolality (mOsm/kg)	2090	2090	2090	2090
pH	5.0 – 6.0	5.0 - 6.0	5.0 - 6.0	5.0 - 6.0
Electrolyte content (mmol)				
Sodium	33.5	67	100.5	134
Potassium	23.5	47	70.5	94
Magnesium	2.65	5.3	7.95	10.6
Calcium	2.65	5.3	7.95	10.6
Zinc	0.02	0.04	0.06	0.08
Chloride	30	60	90	120
Acetate	30	60	90	120
Phosphate	10	20	30	40

賦型劑：Citric acid monohydrate、egg lecithin、glycerol、sodium oleate、注射用水

劑型

三合一靜脈營養注射用乳劑，625 ml、1250 ml、1875 ml、2500 ml。

藥理分類

靜脈補充胺基酸、碳水化合物、脂肪及電解質的乳劑。

適應症

成人在無法使用、不適宜或不充足使用口服、腸道營養劑時，作為靜脈營養治療之熱量、胺基酸、必需脂肪酸、電解質及液體的補充。

禁忌症

下列情形不可給予本產品：

如同其他含碳水化合物的大量點滴輸注液，注射 NuTRIflex Lipid special**可能發生高血糖，應監測血糖值，發生高血糖時應降低輸注速率或合併胰島素治療。**

靜脈輸注胺基酸會使微量元素自尿液排出增加，尤其是銅、鋅，應考慮微量元素的劑量，特別是長期使用靜脈營養。

由於可能發生假性血液凝集的危險，NuTRIflex Lipid special**不可與血液同時經同一管路輸注。**

長期使用時，必須嚴格監控血清電解質、水分平衡、酸鹼平衡、血球計數、凝血狀態及肝功能。

在脂肪未充分自血液清除前抽取血液樣本，則脂肪成份可能影響實驗室檢驗值〔例如：膽紅素、LDH (lactate dehydrogenase)、**血氧飽和濃度〕。**

必要時應補充電解質、維他命及微量元素，由於 NuTRIflex Lipid special**已經含有鋅和鎂，如果與含有這些元素的溶液一齊給予時則應特別小心照顧。**

如同所有靜脈輸液治療，注射 NuTRIflex Lipid special**應嚴格遵守無菌方式。**

NuTRIflex Lipid special**為一種配方複雜的產品，故強烈建議不可再添加其他溶液。**

孕婦及哺乳婦

臨床上尚無相關研究，懷孕婦女使用 NuTRIflex Lipid special**前應考慮其預期之益處及危險。**

若婦女於哺乳期須接受靜脈營養治療，則不建議哺乳。

交互作用

某些藥物，例如胰島素(insulin)**可能妨礙脂肪分解酵素系統作用，此種交互作用在臨床上的重要性很有限。**

給予臨床劑量的肝素(Heparin)**使脂蛋白脂肪分解酵素短暫地釋出而進入循環系統，因此可能使血漿中脂肪分解增加，而造成血清中三酸甘油脂短暫的上升。**

大豆油(Soy-bean oil)**所含之天然維他命**K_1**，可能妨礙coumarin衍生物的治療作用，使用這類藥物的病患應密切監視。**

劑量

依病患之個別需要給予。

成人：

每日最大劑量為每公斤體重35 ml，相當於

- **每天每公斤體重**2.0**公克胺基酸**
- **每天每公斤體重**5.04**公克葡萄糖**
- **每天每公斤體重**1.4**公克脂肪**

NuTRIflex Lipid special**應持續輸注，於最初30分鐘逐步增加輸注速度至所需的速度，以避免合併症發生。**

最大輸注速率為每小時每公斤體重1.7 ml**，相當於**

- **每小時每公斤體重**0.1**公克胺基酸**
- **每小時每公斤體重**0.24**公克葡萄糖**
- **每小時每公斤體重**0.07**公克脂肪**

體重70公斤病患最大輸注速率為每小時119 ml**；相當於每小時輸注胺基酸6.8公克，葡萄糖**17.1**公克，脂肪**4.8**公克**

一般而言，最大輸注劑量不應超過每天每公斤體重 40 kcal**，如果是特殊適應症，例如燒燙傷病患，則可以給予較高劑量。**

給予方式

只能經由中央靜脈輸注。

混合溶液：

將袋子由保護的包裝移出，並以下列步驟進行操作：

- **將袋子攤平於硬的平面上**
- **用雙手壓住並分別打開上方兩個袋子的接合處**
- **將袋子內的成分混合**

準備輸注溶液：

- **將上方兩個空的袋子折到背後**
- **將混合溶液的袋子以其掛環吊掛於點滴架上**
- **移開注射座上的保護蓋，並以正常的操作技術進行輸注**

輸注期間

依照本品所宣稱之適應症其治療期間由醫師依照病情決定。長期給予 NuTRIflex Lipid special**時，須適當補充微量元素與維生素。**

過量用藥

適當地輸注NuTRIflex Lipid special**預期不會發生過量用藥。**

水分及電解質過量的症狀：

低滲透壓的水分過多、電解質不平衡及肺水腫

胺基酸過量的症狀：

胺基酸由腎臟流失，持續的胺基酸不平衡、病態、嘔吐和寒顫

葡萄糖過量的症狀：

高血糖、糖尿、脫水、高滲透壓、高血糖和高滲透壓性昏迷

脂肪過量的症狀：

脂肪給予過量可能造成負荷過量症候群(overload syndrome)**，其特徵〔例如〕發燒、頭痛、腹痛、疲勞、高血脂、肝臟腫大合併 /未合併黃疸、脾臟腫大、肝臟功能異常、貧血、血小板數目減少、白血球數目減少、出血傾向或出血、凝血異常或凝血因子減少〔出血時間、凝固時間、凝血時間等〕，輸注期間血清中三酸甘油脂值不應高於** 3 mmol/l**。**

癌之熱量、胺基酸、必需脂肪酸、電解質及液體的補充。

禁忌症

下列情形不可給予本產品：

- **胺基酸代謝障礙**
- **脂肪代謝障礙**
- **高血鉀症、高血鈉症**
- **代謝不穩定〔例如：嚴重攻擊後症候群，不穩定的糖尿病狀況，不明原因的昏迷〕**
- **對於每小時6單位胰島素治療無反應之高血糖症**
- **酸中毒**
- **肝內膽汁淤積症**
- **嚴重肝功能不全**
- **嚴重腎功能不全且未接受腎臟替代療法者**
- **明顯的心臟功能不全**
- **嚴重出血傾向**
- **心肌梗塞及中風之急性期**
- **急性血栓-栓塞，脂肪栓塞**
- **已知對蛋、大豆蛋白，花生油或其他成份過敏者**

NuTRIflex Lipid special **的成分不可使用於新生兒、嬰兒或2歲以下之兒童。**

一般靜脈營養禁忌症：

- **循環不穩定且威脅生命〔衰竭及休克〕**
- **細胞氧氣供應不足**
- **體液過多電解質、體液不平衡，急性肺水腫，心臟功能不全**

注意事項

注意血清滲透壓上升。

如同所有大量點滴輸注液，心臟、腎臟功能受損的病人注射 NuTRIflex Lipid special**應特別小心，給予本期前應先治療體液、電解質及酸鹼不平衡的情形，例如：水分過多、高血鉀、酸中毒。輸注過快可能會造成體液負荷過多及血清電解質濃度異常，水分過多及肺水腫。**

輸注NuTRIflex Lipid special**期間應監測血清中三酸甘油脂值，輸注前懷疑有脂肪代謝障礙者不應給予，空腹高血脂症為本產品之禁忌症，注射後12小時出現血中三酸甘油脂升高，亦為脂肪代謝障礙。**

脂肪代謝障礙者應小心使用，例如：腎功能不全、糖尿病、胰臟炎、肝功能受損、甲狀腺功能低下（伴隨高三酸甘油脂血症）及敗血症。有以上情形的病人若使用 NuTRIflex Lipid special**，應密切監測血中三酸甘油脂值。**

任何過敏反應的徵象或症狀〔例如：發燒、寒顫、疹子或呼吸困難〕應立刻暫停輸注。

依病人的代謝情形，可能出現高三酸甘油脂血症或血糖上升的情形；注射期間血清中三酸甘油脂值高於 3 mmol/l**，建議降低輸注速率，若血清中三酸甘油脂值仍高於** 3 mmol/l**，則停止輸注，直到其血清值正常。**

注射本劑時，若血糖高於 14 mmol/l (250mg/dl) **亦須減少劑量、降低輸注速率或暫停輸注。**

臟功能異常、貧血、血小板數目異少、白血球數目減少、出血傾向或出血、凝血異常或凝血因子減少〔出血時間、凝固時間、凝血時間等〕，輸注期間血清中三酸甘油脂值不應高於 3 mmol/l。

緊急治療及解毒方法：

劑量給予過量時必須立即停止輸注。視特殊症狀及嚴重度進行後續治療。當症狀消失後，輸注速率應緩慢增加並且更頻繁密切監測。

副作用

注射脂肪乳劑初期的可能反應：體溫輕度上升、潮紅、冷的感覺、寒顫、沒有食慾、噁心、嘔吐、呼吸困難、頭痛、胃痛、骨頭痛、胸部及下背疼痛、血壓下降或上升〔低血壓或高血壓〕、過敏反應〔過敏或皮膚疹〕。

因血中氧氣含量減少造成熱潮紅或皮膚顏色泛藍〔發紺〕是可能發生的副作用。

若發生這些副作用時應停止輸注，情況許可時，應以較慢速度輸注。

應注意是否發生負荷過量症候群，起因為個體之不同的代謝情形、在不同的輸注速度、不同的劑量都可發生不同。

負荷過量症候群與下列症狀有關：肝臟變大〔肝臟腫大〕、合併/未合併黃疸、膜臟變大〔膜臟腫大〕、器官脂肪浸潤、肝臟功能異常、貧血、白血球數目減少、血小板數目減少、出血傾向和出血、凝血因子改變或減少受抑制〔出血時間、凝固時間、凝血時間等〕、發燒、高血脂、頭痛、胃痛、疲倦。

若發生注射部位不適、靜脈炎或血栓靜脈炎時，應考慮更換注射部位。

如果你有其他仍單上沒有提到的副作用，請告知照顧您的醫師或藥師。

貯存

超過標籤上所標示之有效日期後，請勿使用。

溶液混合後應立即使用，混合之溶液於2-8°C以下可存放4天，加上室溫25°C下48小時。

混合後的乳劑於連接注射管路後可立即進行輸注。

NuTRIflex Lipid special為提供單次使用之包裝，未使用完畢之溶液應予丟棄。

如果使用過濾器則必須可適用於脂肪乳劑。

貯存溫度不可高於25°C。

產品不可冷凍，如果已經行冷凍，應予以丟棄。

如果脂肪乳劑裝中已觀察到相的分離（即產生油滴），則不可使用本產品。惟產品包裝無損壞且胺基酸和葡萄糖溶液呈清澈無雜質狀態，方可使用本產品。

請以原外箱包裝避光貯存。

最後修改日期：07. 2014

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B|BRAUN

B. Braun Melsungen AG
34209 Melsungen, Germany

173/12607453/0814

Directions for Use

B. Braun Melsungen AG · 34209 Melsungen, Germany

NuTRIflex Lipid special

Emulsion for infusion

Composition

The ready to use emulsion for infusion contains after mixing of the contents of the individual chambers:

Active ingredients

– from the upper, left chamber	**in 625 ml**	**in 1250 ml**	**in 1875 ml**	**in 2500 ml**
Glucose monohydrate equivalent to anhydrous glucose	99.0 g 90.0 g	198.0 g 180.0 g	297.0 g 270.0 g	396.0 g 360.0 g
Sodium dihydrogen phosphate dihydrate	1.56 g	3.120 g	4.680 g	6.240 g
Zinc acetate dihydrate	4.39 mg	8.78 mg	13.17 mg	17.56 mg
from the upper, right chamber	**in 625 ml**	**in 1250 ml**	**in 1875 ml**	**in 2500 ml**
Soya-bean oil	12.5 g	25.0 g	37.5 g	50.0 g
Medium-chain triglycerides	12.5 g	25.0 g	37.5 g	50.0 g
from the lower chamber	**in 625 ml**	**in 1250 ml**	**in 1875 ml**	**in 2500 ml**
Isoleucine	2.06 g	4.11 g	6.16 g	8.21 g
Leucine	2.74 g	5.48 g	8.22 g	10.96 g
Lysine hydrochloride equivalent to Lysine	2.49 g 1.99 g	4.98 g 3.98 g	7.46 g 5.96 g	9.95 g 7.95 g
Methionine	1.71 g	3.42 g	5.13 g	6.84 g
Phenylalanine	3.08 g	6.15 g	9.22 g	12.29 g
Threonine	1.59 g	3.18 g	4.76 g	6.35 g
Tryptophan	0.50 g	1.00 g	1.50 g	2.00 g
Valine	2.26 g	4.51 g	6.76 g	9.01 g
Arginine	2.37 g	4.73 g	7.09 g	9.45 g
Histidine hydrochloride monohydrate equivalent to Histidine	1.48 g 1.10 g	2.96 g 2.19 g	4.44 g 3.29 g	5.92 g 4.38 g
Alanine	4.25 g	8.49 g	12.73 g	16.98 g
Aspartic acid	1.32 g	2.63 g	3.94 g	5.25 g
Glutamic acid	3.07 g	6.14 g	9.20 g	12.27 g
Glycine	1.45 g	2.89 g	4.33 g	5.78 g
Proline	2.98 g	5.95 g	8.93 g	11.90 g
Serine	2.63 g	5.25 g	7.88 g	10.50 g
Sodium hydroxide	0.732 g	1.464 g	2.196 g	2.928 g
Sodium chloride	0.237 g	0.473 g	0.710 g	0.946 g
Sodium acetate trihydrate	0.157 g	0.313 g	0.470 g	0.626 g
Potassium acetate	2.306 g	4.611 g	6.917 g	9.222 g
Magnesium acetate tetrahydrate	0.569 g	1.137 g	1.706 g	2.274 g
Calcium chloride dihydrate	0.390 g	0.779 g	1.168 g	1.558 g
	in 625 ml	**in 1250 ml**	**in 1875 ml**	**in 2500 ml**
Amino acid content [g]	35.9	71.8	107.7	143.6
Total nitrogen content [g]	5	10	15	20
Carbohydrate content [g]	90	180	270	360
Lipid content [g]	25	50	75	100
	in 625 ml	**in 1250 ml**	**in 1875 ml**	**in 2500 ml**
Energy in the form of lipid [kJ (kcal)]	995 (240)	1990 (475)	2985 (715)	3980 (950)
Energy in the form of carbohydrate [kJ (kcal)]	1510 (360)	3015 (720)	4520 (1080)	6030 (1440)
Energy in the form of amino acids [kJ (kcal)]	585 (140)	1170 (280)	1755 (420)	2340 (560)
Non-protein energy [kJ (kcal)]	2505 (600)	5005 (1195)	7510 (1795)	10010 (2390)
Total energy [kJ (kcal)]	3090 (740)	6176 (1475)	9265 (2215)	12350 (2950)
Osmolality (mOsm/kg)	2090	2090	2090	2090
pH	5.0 – 6.0	5.0 - 6.0	5.0 - 6.0	5.0 - 6.0
Electrolytes (mmol)				
Sodium	33.5	67	100.5	134
Potassium	23.5	47	70.5	94
Magnesium	2.65	5.3	7.95	10.6
Calcium	2.65	5.3	7.95	10.6
Zinc	0.02	0.04	0.06	0.08
Chloride	30	60	90	120
Acetate	30	60	90	120
Phosphate	10	20	30	40

Excipients:
Citric acid monohydrate, egg lecithin, glycerol, sodium oleate, water for injections

Pharmaceutical form

Emulsion for intravenous infusion in three-chamber bags containing 625 ml, 1250 ml, 1875 ml or 2500 ml.

Pharmaco-therapeutic group

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 Lipid special should not be given simultaneously with blood in the same infusion set due to the risk of pseudoagglutination.
Moreover controls of the serum electrolytes, the water balance, the acid-base balance and – during long-term administration – of blood cell counts, coagulation status and hepatic function are necessary.
The fat content may interfere with certain laboratory measurements (e.g. bilirubin, lactate dehydrogenase, oxygen saturation). if blood is sampled before fat has been adequately cleared from the blood stream.
Substitution of electrolytes, vitamins and trace elements may be necessary as required.
As NuTRIflex Lipid special contains zinc and magnesium, care should be taken when it is co-administered with solutions containing these elements.
As with all intravenous solutions strict aseptic precautions are necessary for the infusion of NuTRIflex® Lipid special.
NuTRIflex Lipid special is a preparation of complex composition. It is, therefore, strongly advisable not to add other solutions.

Pregnancy and lactation

Preclinical studies have not been performed with NuTRIflex Lipid special. The prescriber should consider the benefit/ risk relationship before administering NuTRIflex Lipid special to pregnant women.
Breast-feeding is not recommended if women need parenteral nutrition in that time.

Interactions

Some drugs, like insulin, may interfere with the body's lipase system. This kind of interaction seems, however, to be of only limited clinical importance.
Heparin given in clinical doses causes a transient release of lipoprotein lipase into the circulation. This may result initially in increased plasma lipolysis followed by a transient decrease in triglyceride clearance.
Soya-bean oil has a natural content of vitamin K_1. This may interfere with the therapeutic effect of coumarin derivatives which should be closely monitored in patients treated with such drugs.

Dosage

The dosage is adjusted according to the patients' individual requirements.

Adults:
The maximum daily dose is 35 ml/kg body weight, corresponding to
– 2.0 g amino acids /kg body weight per day,
– 5.04 g glucose /kg body weight per day,
– 1.4 g lipid /kg body weight per day.
It is recommended that NuTRIflex® Lipid special be administered continuously. A stepwise increase of the infusion rate over the first 30 minutes up to the desired infusion rate helps to avoid complications.
The maximum rate of infusion is 1.7 ml/kg body weight per hour, corresponding to
– 0.1 g amino acids /kg body weight per hour,
– 0.24 g glucose /kg body weight per hour,
– 0.07 g lipid /kg body weight per hour.
For a patient weighing 70 kg this corresponds to an infusion rate of 119 ml/kg body weight per hour. The amount of amino acid administered is then 6.8 g/hour, of glucose 17.1 g/hour and of lipid 4.8 g/hour.
In general, it is recommended that the maximum amount of energy should not exceed 40 kcal/kg BW and day. If specially indicated e.g. for burned patients higher dosage is possible.

Method of administration
For central venous infusion only
Preparation of the mixed solution:
Remove the bag from its protective pack and proceed as follows:
- open out the bag and lay on a solid surface
- open the peel seals to the two upper chambers by using pressure with both hands
- briefly mix the contents of the bag together

Preparation for infusion:
- fold the two empty chambers backwards
- hang the mixing bag on the infusion stand by the centre hanging loop
- remove the protective cap from the run-out port and carry out infusion using the normal technique

Duration of use
The duration of treatment for the indications stated is not limited. During long-term administration of NuTRIflex® Lipid special it is necessary to supply appropriate replacement of trace elements and vitamins.

Overdose

Overdose of NuTRIflex Lipid special is not to be expected on proper administration.

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

Pharmaco-therapeutic group
Emulsion for intravenous supply of amino acids, carbohydrates, fat and electrolytes.

Indications
Supply of energy, essential fatty acids, 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,
– disturbances of lipid metabolism,
– hyperkalaemia; hypernatraemia,
– unstable metabolism (e.g. severe postaggression syndrome, unstabilized diabetic metabolic situation, coma of unknown origin),
– hyperglycaemia not responding to insulin doses of up to 6 units insulin/hour,
– acidosis,
– intrahepatic cholestasis,
– severe hepatic insufficiency,
– severe renal insufficiency in absence of renal replacement therapy,
– manifest cardiac insufficiency,
– aggravating haemorrhagic diatheses,
– acute phases of cardiac infarction and stroke,
– acute event of thrombo-embolism, lipid embolism,
– known hypersensitivity to egg or soya-bean protein, peanut oil or to any of the excipients.

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

General contraindications 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 special precautions for use
Caution should be exercised in cases of increased serum osmolarity
As for all large-volume infusion solutions NuTRIflex Lipid special 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.
The serum triglyceride concentration should be monitored when infusing NuTRIflex® Lipid special. Fasting lipaemia should be excluded in patients with suspected disturbances of lipid metabolism before starting infusion. The administration of lipids is contraindicated if there is fasting lipaemia. The presence of hypertriglyceridaemia 12 hours after lipid administration also indicates a disturbance of lipid metabolism.
NuTRIflex Lipid special should be administered cautiously to patients with disturbances of lipid metabolism, e.g. renal insufficiency, diabetes mellitus, pancreatitis, impaired liver function, hypothyroidism (with hypertriglyceridemia) and sepsis. If NuTRIflex Lipid special is given to patients with these conditions, close monitoring of serum triglycerides is mandatory.
Any sign or symptom of anaphylactic reaction (such as fever, shivering, rash or dyspnoea) should lead to immediate interruption of the infusion.
Depending on the patient's metabolic condition, occasional hypertriglyceridaemia or increases of the blood glucose concentration may occur. If the plasma triglyceride concentration rises to more than 3 mmol/l during administration of lipid it is recommended that the infusion rate should be reduced. Should the plasma triglyceride concentration remain above 3 mmol/l the administration should be stopped until the level normalizes.
A dose reduction or interruption of administration is also indicated if the blood glucose concentration rises to more than 14 mmol/l (250 mg/dl) when administering the product.
As with all solutions containing carbohydrates the administration of NuTRIflex Lipid special 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.
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.

Symptoms of lipid overdose:
Lipid overdose may lead to the overload syndrome, characterised (for example) by fever, headache, abdominal pain, fatigue, hyperlipaemia, hepatomegaly with or without jaundice, splenomegaly, pathological disturbances of liver function, anaemia, reduction in platelet count, reduction in white cell count, haemorrhagic diathesis and haemorrhage, alteration or depression of blood coagulation factors (bleeding time, coagulation time, prothrombin time etc.). The plasma triglyceride concentration should not exceed 3 mmol/l during infusion.

Emergency treatment, antidotes
Immediate stop of infusion is indicated in the case of 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
Possible early reactions on the administration of lipid emulsions are: slight increase in temperature, flush, cold feeling, shivering, loss of appetite, nausea, vomiting, respiratory distress, headache, backache, bone pain, pain in the chest and lumbar region, fall or increase in blood pressure (hypotension, hypertension), hypersensitivity reactions (e.g. anaphylactic reactions, dermal eruptions).
Hot flushes or bluish discoloration of the skin due to reduced oxygen content of the blood (cyanosis) can occur as side effects.
If these side effects occur the infusion should be discontinued or, if appropriate, the infusion should be continued at a lower dose level.
Attention should be paid to the possibility of an overloading syndrome This can occur as a result of individually varying, genetically determined metabolic conditions and can occur at different rates and after differing doses depending on previous disorders.
Overloading syndrome is associated with the following symptoms: enlargement of the liver (hepatomegaly) with or without jaundice (icterus), enlargement of the spleen (splenomegaly), fatty infiltration of organs, pathological hepatic function parameters, anaemia, reduction of white cell count (leucopenia), reduction of platelet count (thrombocytopenia), a tendency to haemorrhage and haemorrhages, alterations or reduction in the blood coagulation factors (bleeding time, coagulation time, prothrombin time etc.), fever, hyperlipaemia, headache, stomach-ache, fatigue.
Please inform your doctor or pharmacist if you notice any undesirable effect that is not mentioned in this leaflet.

Instructions for storage / use / handling
Do not use the product beyond the expiry date stated on the labelling.
The ready-to-use emulsion can be stored for 4 days at 2 – 8 °C plus 48 hours at 25 °C.
The emulsion is to be used immediately after connecting the container to the giving set.
NuTRIflex Lipid special is supplied in single dose containers. Unused residues must be discarded.
If filters are used they must be lipid-permeable.
Do not store above 25°C.
Do not freeze. If accidentally frozen, discard the bag.
Keep bags in the outer carton in order to protect from light.
Only use bags that are undamaged and in which the amino acid and glucose solutions are clear. Do not use bags where there is discernible phase separation (oil drops) in the chamber containing lipid emulsion.

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