PACKAGE LEAFLET

Package leaflet: Information for the user

Lipoflex special emulsion for infusion

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Lipoflex special is and what it is used for
2. What you need to know before you use Lipoflex special
3. How to use Lipoflex special
4. Possible side effects
5. How to store Lipoflex special
6. Contents of the pack and other information

1. What Lipoflex special is and what it is used for

Lipoflex special contains fluids and substances called amino acids, electrolytes and fatty acids that are essential for the body to grow or to recover. It also contains calories in the form of carbohydrates and fats.

You are given this medicine when you are unable to eat food normally. There are many situations when this might be the case, for example when you are recovering from surgery, injuries or burns, or when you are unable to absorb food from your stomach and gut.

This emulsion can be given to adults, adolescents and children over 2 years of age.

2. What you need to know before you use Lipoflex special

Do not use Lipoflex special
- if you are allergic to any of the active substances, to egg, peanut or soybean or to any of the other ingredients of this medicine (listed in section 6).
- This medicine must not be given to newborn infants, infants and toddlers under two years old.

Also, do not use this medicine if you suffer from any of the following:
- life-threatening blood circulation problems such as those that can occur if you are in a state of collapse or shock
- heart attack or stroke
- severely impaired blood clotting function, bleeding risk (severe coagulopathy, aggravating haemorrhagic diatheses)
- blocking of blood vessels by blood clots or fat (embolism)
- severe liver failure
- impaired bile flow (intrahepatic cholestasis)
- severe kidney failure in the absence of kidney replacement therapy
- disturbances of your body salt composition

- fluid deficit or excess water in your body
- water on your lungs (pulmonary oedema)
- severe heart failure
- certain metabolic disorders such as
  - too much lipid (fat) in the blood
  - inborn errors of amino acid metabolism
  - abnormally high blood sugar level that needs more than 6 units of insulin per hour to be controlled
  - abnormalities of metabolism that may occur after operations or injuries
  - coma of unknown origin
  - insufficient supply of oxygen to tissues
  - abnormally high acid level in the blood.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Lipoflex special.
Please inform your doctor if:
- you have heart, liver or kidney problems
- you suffer from certain types of metabolic disorders such as diabetes, abnormal blood fat values and disorders of your body fluid and salt composition or your acid-base balance.

You will be monitored closely to detect early signs of an allergic reaction (such as fever, shivering, rash, or shortness of breath) when you receive this medicine.

Further monitoring and tests such as various examinations of blood samples will be applied to make sure that your body handles the administered foodstuffs properly.

The nursing staff may also take measures to ensure that your body's fluid and electrolyte requirements are met. In addition to this medicine you may receive further nutrients (foodstuffs) in order to fully cover your requirements.

Children

This medicine must not be given to newborn infants, infants and toddlers under two years old.

Other medicines and Lipoflex special

Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines.

Lipoflex special can interact with some other medicines. Please tell your doctor, pharmacist or nurse if you are taking or receiving any of the following:
- insulin
- heparin
- medicines that prevent undesirable blood clotting such as warfarin or other coumarin derivatives
- medicines to promote urine flow (diuretics)
- medicines to treat high blood pressure (ACE inhibitors)
- medicines to treat high blood pressure or heart problems (angiotensin-II-receptor antagonists)
- medicines used in organ transplants such as ciclosporin and tacrolimus
- medicines to treat inflammation (corticosteroids)
- hormone preparations that affect your fluid balance (adrenocorticotropic hormone or ACTH)

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. If you are pregnant, you will receive this medicine only if the doctor or pharmacist considers it absolutely necessary for your recovery. There is no data available about the use of Lipoflex special in pregnant women.

Breast-feeding is not recommended for mothers on parenteral nutrition.

Driving and using machines

This medicineis normally given to immobile patients, e.g. in a hospital or clinic which would exclude driving or using machines. However, this medicine has no effect on the ability to drive and use machines.

Lipoflex special contains sodium
This medicine contains 771 mg sodium (main component of cooking/table salt) in each 625 ml bag. This is equivalent to 39% of the recommended maximum daily dietary intake of sodium for an adult.
The maximum recommended daily dose of this medicinal product contains 3020 mg sodium (found in table salt). This is equivalent to 151% of the adult recommended maximum daily dietary intake for sodium.
Talk to your doctor or pharmacist if you need one or more bags daily for a prolonged period, especially if you have been advised to follow a low salt (sodium) diet.

3. How to use Lipoflex special

This medicine is administered by intravenous infusion (drip), that is, through a small tube directly into a vein. This medicine will be administered through one of your large (central) veins only.

Your doctor or pharmacist will decide how much of this medicine you need and for how long you will require treatment with this medicine.

Use in children

This medicine must not be given to newborn infants, infants and toddlers under two years old.
Your doctor will decide how much of this medicine your child needs and for how long your child will require treatment with this medicine.

If you use more Lipoflex special than you should

If you have received too much of this medicine you may suffer from a so-called ‘overload syndrome’ and the following symptoms:
- fluid excess and electrolyte disorders
- water on your lungs (pulmonary oedema)
- loss of amino acids through the urine and disturbed amino acid balance
- vomiting, feeling sick
- shivering
- high blood sugar level
- glucose in the urine
- fluid deficit
- blood much more concentrated than normal (hyperosmolality)

- impairment or loss of consciousness due to extremely high blood sugar
- enlargement of the liver (hepatomegaly) with or without jaundice (icterus)
- enlargement of the spleen (splenomegaly)
- fat deposition in the inner organs
- abnormal values of liver function tests
- reduction of red blood cell count (anaemia)
- reduction of white blood cell count (leucopenia)
- reduction of blood platelet count (thrombocytopenia)
- increase of immature red blood cells (reticulocytosis)
- rupture of blood cells (haemolysis)
- bleeding or a tendency to bleeding
- impairment of blood coagulation (as can be seen by changes of bleeding time, coagulation time, prothrombin time etc.)
- fever
- high blood fat levels
- loss of consciousness

If any of these symptoms occur, the infusion must be stopped immediately.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following side effects may be serious. If any of the following side effects occur, tell your doctor immediately, he will stop giving you this medicine:

Rare (may affect up to 1 in 1,000 people):
- allergic reactions, for example skin reactions, shortness of breath, swelling of the lips, mouth, and throat, difficulty breathing

Other side effects include:

Uncommon (may affect up to 1 in 100 people):
- feeling sick, vomiting, loss of appetite

Rare (affects 1 to 10 users in 10,000):
- increased tendency for your blood to clot
- bluish discolouration of the skin
- shortness of breath
- headache
- flushing
- reddening of skin (erythema)
- sweating
- chills
- feeling cold
- high body temperature
- drowsiness
- pain in the chest, back, bones or lumbar region
- decrease or increase in blood pressure

Very rare (may affect up to 1 in 10,000 people):
- abnormally high blood fat or blood sugar values
- high levels of acidic substances in your blood
- Too much lipid can lead to fat overload syndrome, for more information on this please see under the heading "If you use more Lipoflex special than you should" in section 3. Symptoms normally disappear when the infusion is stopped.

Not known (frequency cannot be estimated from the available data):
- reduction of white blood cell count (leucopenia)
- reduction of blood platelet count (thrombocytopenia)
- impaired bile flow (cholestasis)

Reporting of side effects
If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Lipoflex special

Keep this medicine out of the sight and reach of children.
Do not store above 25 °C.
Do not freeze. If accidentally frozen, discard the bag.
Keep the bag in the protective overwrap in order to protect from light.
Do not use this medicine after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

6. Contents of the pack and other information

What Lipoflex special contains

The active substances in the ready-for-use mixture are:

from the top chamber (glucose solution)	in 1000 ml	in 625 ml	in 1250 ml	in 1875 ml
Glucose monohydrate equivalent to glucose	158.4 g 144.0 g	99.00 g 90.00 g	198.0 g 180.0 g	297.0 g 270.0 g
Sodium dihydrogen phosphate dihydrate	2.496 g	1.560 g	3.120 g	4.680 g
Zinc acetate dihydrate	7.024 mg	4.390 mg	8.780 mg	13.17 mg

from the middle chamber (fat emulsion)	in 1000 ml	in 625 ml	in 1250 ml	in 1875 ml
Soya-bean oil, refined	20.00 g	12.50 g	25.00 g	37.50 g
Medium-chain triglycerides	20.00 g	12.50 g	25.00 g	37.50 g

from the bottom chamber (amino acid solution)	in 1000 ml	in 625 ml	in 1250 ml	in 1875 ml

Isoleucine	3.284 g	2.053 g	4.105 g	6.158 g
Leucine	4.384 g	2.740 g	5.480 g	8.220 g
Lysine hydrochloride	3.980 g	2.488 g	4.975 g	7.463 g
equivalent to lysine	3.186 g	1.991 g	3.982 g	5.973 g
Methionine	2.736 g	1.710 g	3.420 g	5.130 g
Phenylalanine	4.916 g	3.073 g	6.145 g	9.218 g
Threonine	2.540 g	1.588 g	3.175 g	4.763 g
Tryptophan	0.800 g	0.500 g	1.000 g	1.500 g
Valine	3.604 g	2.253 g	4.505 g	6.758 g
Arginine	3.780 g	2.363 g	4.725 g	7.088 g
Histidine hydrochloride monohydrate	2.368 g	1.480 g	2.960 g	4.440 g
equivalent to histidine	1.753 g	1.095 g	2.191 g	3.286 g
Alanine	6.792 g	4.245 g	8.490 g	12.73 g
Aspartic acid	2.100 g	1.313 g	2.625 g	3.938 g
Glutamic acid	4.908 g	3.068 g	6.135 g	9.203 g
Glycine	2.312 g	1.445 g	2.890 g	4.335 g
Proline	4.760 g	2.975 g	5.950 g	8.925 g
Serine	4.200 g	2.625 g	5.250 g	7.875 g
Sodium hydroxide	1.171 g	0.732 g	1.464 g	2.196 g
Sodium chloride	0.378 g	0.237 g	0.473 g	0.710 g
Sodium acetate trihydrate	0.250 g	0.157 g	0.313 g	0.470 g
Potassium acetate	3.689 g	2.306 g	4.611 g	6.917 g
Magnesium acetate tetrahydrate	0.910 g	0.569 g	1.137 g	1.706 g
Calcium chloride dihydrate	0.623 g	0.390 g	0.779 g	1.169 g

Electrolytes	in 1000 ml	in 625 ml	in 1250 ml	in 1875 ml
Sodium	53.6 mmol	33.5 mmol	67 mmol	100.5 mmol
Potassium	37.6 mmol	23.5 mmol	47 mmol	70.5 mmol
Magnesium	4.2 mmol	2.65 mmol	5.3 mmol	7.95 mmol
Calcium	4.2 mmol	2.65 mmol	5.3 mmol	7.95 mmol
Zinc	0.03 mmol	0.02 mmol	0.04 mmol	0.06 mmol
Chloride	48 mmol	30 mmol	60 mmol	90 mmol
Acetate	48 mmol	30 mmol	60 mmol	90 mmol
Phosphate	16 mmol	10 mmol	20 mmol	30 mmol

Amino acid content	56.0 g	35.0 g	70.1 g	105.1 g
Nitrogen content	8 g	5 g	10 g	15 g
Carbohydrate content	144 g	90 g	180 g	270 g
Lipid content	40 g	25 g	50 g	75 g

Energy in the form of lipids	1590 kJ (380 kcal)	995 kJ (240 kcal)	1990 kJ (475 kcal)	2985 kJ (715 kcal)
Energy in the form of carbohydrates	2415 kJ (575 kcal)	1510 kJ (360 kcal)	3015 kJ (720 kcal)	4520 kJ (1080 kcal)
Energy in the form of amino acids	940 kJ (225 kcal)	585 kJ (140 kcal)	1170 kJ (280 kcal)	1755 kJ (420 kcal)
Non-protein energy	4005 kJ (955 kcal)	2505 kJ (600 kcal)	5005 kJ (1195	7505 kJ (1795 kcal)

			kcal)	
Total energy	4945 kJ (1180 kcal)	3090 kJ (740 kcal)	6175 kJ (1475 kcal)	9260 kJ (2215 kcal)

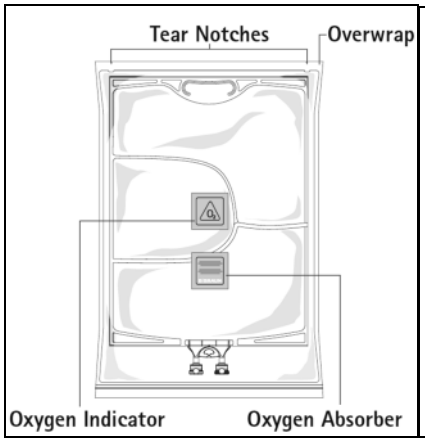
Osmolality	2115 mOsm/kg	2115 mOsm/kg	2115 mOsm/kg	2115 mOsm/kg
Theoretical osmolarity	1545 mOsm/l	1545 mOsm/l	1545 mOsm/l	1545 mOsm/l
pH	5.0 - 6.0	5.0 - 6.0	5.0 - 6.0	5.0 - 6.0

The other ingredients are citric acid monohydrate (for pH adjustment), egg phospholipids for injection, glycerol, sodium oleate, all-rac-alpha-tocopherol and water for injections.

What Lipoflex special looks like and contents of the pack

The ready-to-use product is an emulsion for infusion, i.e. it is administered through a small tube into a vein.

Lipoflex special is supplied in flexible multichamber bags containing:
– 625 ml (250 ml of amino acids solution + 125 ml of fat emulsion + 250 ml of glucose solution)
– 1250 ml (500 ml of amino acids solution + 250 ml of fat emulsion + 500 ml of glucose solution)
– 1875 ml (750 ml of amino acids solution + 375 ml of fat emulsion + 750 ml of glucose solution)



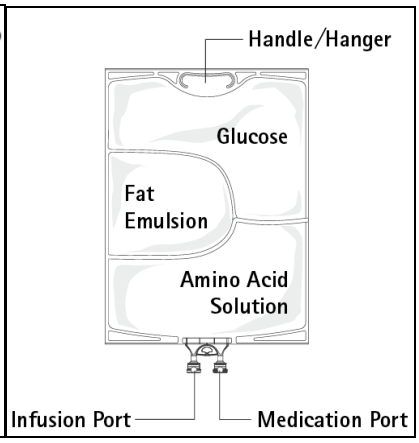


Figure A Figure B

Figure A: The multichamber bag is packed in a protective overwrap. An oxygen absorber and an oxygen indicator are placed between the bag and the overwrap; the oxygen absorber sachet is made of inert material and contains iron hydroxide.

Figure B: The top chamber contains a glucose solution, the middle chamber contains a fat emulsion, and the bottom chamber contains an amino acid solution.

The glucose and the amino acid solutions are clear and colourless or straw-coloured. The fat emulsion is milky-white.

The top chamber and the middle chamber can be connected with the bottom chamber by opening the intermediate seams (peel seams).

The design of the bag permits mixing of the amino acids, glucose, lipids and electrolytes in a single chamber. Opening the peel seams results in sterile mixing to form an emulsion.

The different container sizes are presented in cartons containing five bags.
Pack sizes: 5 x 625 ml, 5 x 1250 ml and 5 x 1875 ml
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

B. Braun Melsungen AG
Carl-Braun-Str. 1
34212 Melsungen, Germany

Postal address:
34209 Melsungen, Germany

Tel.: +49-(0)-5661-71-0
Fax: +49-(0)-5661-71-4567

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (GB and NI) under the following names:

Austria	Nutriflex Lipid special B.Braun Emulsion zur Infusion
Belgium	Nutriflex Lipid special, 56 g/l Amino + 144 g/l G, emulsie voor infusie
Denmark	Lipoflex special
Finland	Nutriflex Lipid 56/144/40 infuusioneste, emulsio
France	REANUTRIFLEX E, émulsion pour perfusion
Germany	NuTRIflex Lipid special novo Emulsion zur Infusion
Iceland	Nutriflex Lipid 56/144 special innrennslislyf, fleyti
Italy	LIPOFLEX AA56/ G144 Emulsione per infusione
Luxembourg	NuTRIflex Lipid special novo Emulsion zur Infusion
Netherlands	Nutriflex Lipid special, 56 g/l Amino+ 144 g/l G, emulsie voor infusie
Norway	Lipoflex special infusjonsvæske, emulsjon
Poland	Lipoflex special
Spain	Lipoflex special emulsión para perfusión EFG
Sweden	Nutriflex Lipid 56/144/40 infusionsvätska, emulsion
United Kingdom (GB and NI)	Lipoflex special emulsion for infusion

This leaflet was last revised in 07/2026

The following information is intended for healthcare professionals only:

No special requirements for disposal.

Parenteral nutrition products should be visually inspected for damage, discolouration and emulsion instability before use.

Do not use bags which are damaged. Overwrap, primary bag and the peel seams between the chambers should be intact. Only use if the amino acid and glucose solutions are clear and colourless up to straw-coloured and the lipid emulsion is homogenous with milky white appearance. Do not use if the solutions contain particulate matter.

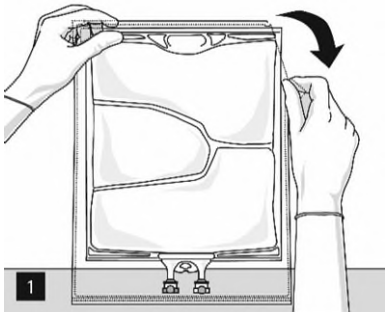
After mixing the three chambers, do not use if the emulsion shows discolouration or signs of phase separation (oil drops, oil layer). Stop the infusion immediately in case of discolouration of the emulsion or signs of phase separation.

Before opening the overwrap, check the colour of the oxygen indicator (see Figure A). Do not use if the oxygen indicator turned pink. Use only if the oxygen indicator is yellow.

Preparation of the mixed emulsion

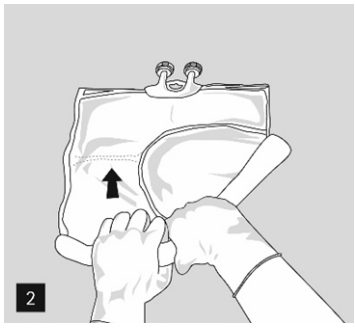
Strict adherence to aseptic handling principles must be complied with.

To open: Tear overwrap starting from the tear notches (Fig. 1). Remove the bag from its protective overwrap. Discard overwrap, oxygen indicator, and oxygen absorber.

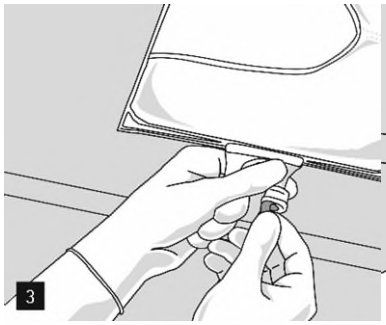


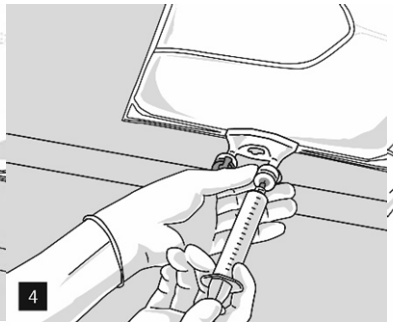
Visually inspect the primary bag for leaks. Leaky bags must be discarded, since the sterility cannot be guaranteed.

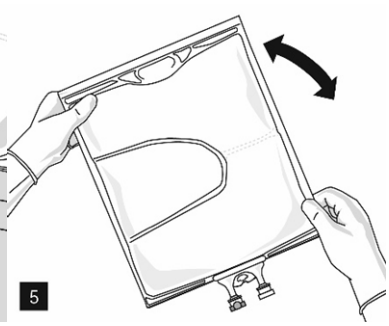
Mixing of the bag and additions of additives
To open and mix the chambers sequentially, roll the bag with both hands, starting first by opening the peel seam that separates the top chamber (glucose) and the bottom chamber (amino acids) (Fig. 2).

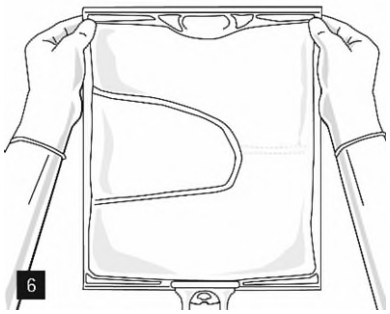


After removing the aluminium seal (Fig. 3) one can add compatible water-soluble additives via the medication port (Fig. 4) to the clear aqueous solutions. Mix the contents thoroughly (Fig.5) and visually inspect the mixture for precipitations (Fig. 6). Only clear solution must be used.

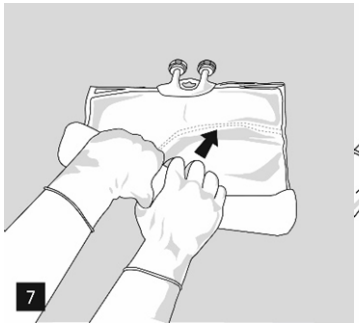


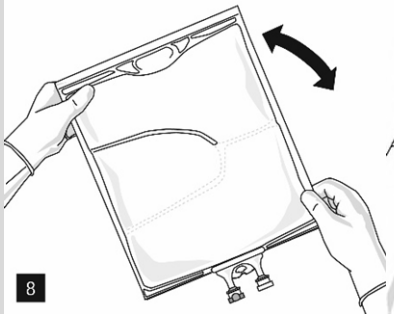


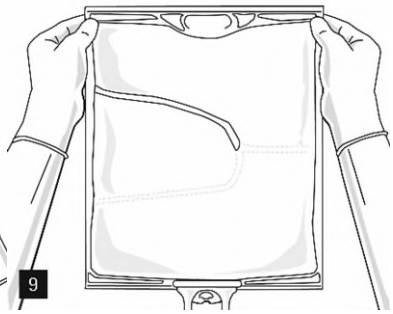




Then continue applying pressure so that the peel seam separating the middle chamber (lipids) and the bottom chamber opens (Fig. 7). The mixture is a milky white homogenous oil-in-water emulsion. After all chambers are mixed one can add compatible additives via the medication port (Fig. 4). Mix the contents thoroughly (Fig. 8) and visually inspect the mixture (Fig. 9).







Compatibility data for different additives (e.g. electrolytes, trace elements, vitamins) and the corresponding shelf life of such admixtures can be provided on demand by the manufacturer.

Preparation for infusion

The emulsion should always be brought to room temperature prior to infusion.

Remove the aluminium foil (Fig. 10) from the infusion port and attach the infusion set (Fig. 11). Use a non-vented infusion set or close the air vent when using a vented set. Hang the bag on an infusion stand (Fig. 12) and carry out infusion using the standard technique.

For single use only. Container and unused residues must be discarded after use.

Do not reconnect partially used containers.

The medicinal product must be administered via a lipid-permeable filter with a pore size of 1.2 µm.

Shelf life after removing the protective overwrap and after mixing of contents of the bag

Chemical and physicochemical in-use stability of the mixture of amino acids, glucose and fat was demonstrated for 7 days at 2-8 °C and additional 2 days at 25 °C.

Shelf life after admixture of compatible additives

From a microbiological point of view, the product should be used immediately after admixture of additives. If not used immediately after admixture of additives, in-use storage times and conditions prior to use are the responsibility of the user.

The emulsion is to be used immediately after opening of the container.

The recommended duration of infusion for a parenteral nutrition bag is maximum 24 h.

This medicinal product must not be mixed with other medicinal products for which compatibility has not been documented.

This medicinal product should not be given simultaneously with blood in the same infusion set due to the risk of pseudoagglutination.