

Package leaflet: Information for the user

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

1. What Nutriflex Omega special is and what it is used for

Nutriflex Omega 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 Nutriflex Omega special 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 solution is given to adults.

2. What you need to know before you use Nutriflex Omega special

Do not use Nutriflex Omega special

- If you are allergic to any of the active substances, to egg, peanut, soybean or fish 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 Nutriflex Omega special 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 (severe hypertriglyceridaemia)
 - 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 before using Nutriflex Omega 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 Nutriflex Omega special you may receive further nutrients (foodstuffs) in order to fully cover your requirements.

Children and adolescents

Safety and efficacy in children and adolescents have not been established. This medicine must not be given to newborn infants, infants and toddlers under two years old.

Other medicines and Nutriflex Omega special

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

Nutriflex Omega special can interact with some other medicines. Please tell your doctor 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 (adrenocorticotrophic hormone [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 for advice before taking this medicine. If you are pregnant you will receive this medicine only if the doctor considers it absolutely necessary for your recovery. There is no data available about the use of Nutriflex Omega special in pregnant women.

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

Driving and using machines

Nutriflex Omega special is 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.

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

3. How to use Nutriflex Omega 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 will decide how much of this medicine you need and for how long you will require treatment with this medicine.

Use in children and adolescents

This medicine must not be given to newborn infants, infants and toddlers under two years old. Safety and efficacy in children and adolescents have not been established.

If you use more Nutriflex Omega 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.

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 (affects 1 to 10 users in 10,000):

- Allergic reactions, for example skin reactions, shortness of breath, swelling of the lips, mouth and throat, difficulty breathing

Other side effects include:

Uncommon (affects 1 to 10 users in 1,000):

- 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 (affects less than 1 user in 10,000):

- 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 Nutriflex Omega 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [the national reporting system listed in Appendix V](#).

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Nutriflex Omega special

Keep this medicine out of the sight and reach of children.

Do not store above 25 °C. Keep the bags in the outer carton in order to protect from light.

Do not freeze. If accidentally frozen, discard the bag.

Do not use this medicine after the expiry date which is stated on the label.

6. Contents of the pack and other information

What Nutriflex Omega special contains

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

<i>from the upper, left-hand chamber (glucose solution)</i>	in 1000 ml	in 625 ml	in 1250 ml	in 1875 ml	in 2500 ml
Glucose monohydrate	158.4 g	99.00 g	198.0 g	297.0 g	396.0 g
equivalent to glucose	144.0 g	90.00 g	180.0 g	270.0 g	360.0 g
Sodium dihydrogen phosphate dihydrate	2.496 g	1.560 g	3.120 g	4.680 g	6.240 g
Zinc acetate dihydrate	7.024 mg	4.390 mg	8.780 mg	13.17 mg	17.56 mg

<i>from the upper, right-hand chamber (fat emulsion)</i>	in 1000 ml	in 625 ml	in 1250 ml	in 1875 ml	in 2500 ml
Medium-chain triglycerides	20.00 g	12.50 g	25.00 g	37.50 g	50.00 g
Soya-bean oil, refined	16.00 g	10.00 g	20.00 g	30.00 g	40.00 g
Omega-3-acid triglycerides	4.000 g	2.500 g	5.000 g	7.500 g	10.00 g

from the lower chamber (amino acid solution)	in 1000 ml	in 625 ml	in 1250 ml	in 1875 ml	in 2500 ml
Isoleucine	3.284 g	2.053 g	4.105 g	6.158 g	8.210 g
Leucine	4.384 g	2.740 g	5.480 g	8.220 g	10.96 g
Lysine hydrochloride equivalent to lysine	3.980 g 3.186 g	2.488 g 1.991 g	4.975 g 3.982 g	7.463 g 5.973 g	9.950 g 7.962 g
Methionine	2.736 g	1.710 g	3.420 g	5.130 g	6.840 g
Phenylalanine	4.916 g	3.073 g	6.145 g	9.218 g	12.29 g
Threonine	2.540 g	1.588 g	3.175 g	4.763 g	6.350 g
Tryptophan	0.800 g	0.500 g	1.000 g	1.500 g	2.000 g
Valine	3.604 g	2.253 g	4.505 g	6.758 g	9.010 g
Arginine	3.780 g	2.363 g	4.725 g	7.088 g	9.450 g
Histidine hydrochloride monohydrate equivalent to histidine	2.368 g 1.753 g	1.480 g 1.095 g	2.960 g 2.191 g	4.440 g 3.286 g	5.920 g 4.381 g
Alanine	6.792 g	4.245 g	8.490 g	12.73 g	16.98 g
Aspartic acid	2.100 g	1.313 g	2.625 g	3.938 g	5.250 g
Glutamic acid	4.908 g	3.068 g	6.135 g	9.203 g	12.27 g
Glycine	2.312 g	1.445 g	2.890 g	4.335 g	5.780 g
Proline	4.760 g	2.975 g	5.950 g	8.925 g	11.90 g
Serine	4.200 g	2.625 g	5.250 g	7.875 g	10.50 g
Sodium hydroxide	1.171 g	0.732 g	1.464 g	2.196 g	2.928 g
Sodium chloride	0.378 g	0.237 g	0.473 g	0.710 g	0.946 g
Sodium acetate trihydrate	0.250 g	0.157 g	0.313 g	0.470 g	0.626 g
Potassium acetate	3.689 g	2.306 g	4.611 g	6.917 g	9.222 g
Magnesium acetate tetrahydrate	0.910 g	0.569 g	1.137 g	1.706 g	2.274 g
Calcium chloride dihydrate	0.623 g	0.390 g	0.779 g	1.169 g	1.558 g

	in 1000 ml	in 625 ml	in 1250 ml	in 1875 ml	in 2500 ml
Amino acid content [g]	56.0	35.1	70.1	105.1	140.1
Nitrogen content [g]	8	5	10	15	20
Carbohydrate content [g]	144	90	180	270	360
Lipid content [g]	40	25	50	75	100

<i>Electrolytes [mmol]</i>	in 1000 ml	in 625 ml	in 1250 ml	in 1875 ml	in 2500 ml
Sodium	53.6	33.5	67	100.5	134
Potassium	37.6	23.5	47	70.5	94
Magnesium	4.2	2.65	5.3	7.95	10.6
Calcium	4.2	2.65	5.3	7.95	10.6
Zinc	0.03	0.02	0.04	0.06	0.08
Chloride	48	30	60	90	120
Acetate	48	30	60	90	120
Phosphate	16	10	20	30	40

	in 1000 ml	in 625 ml	in 1250 ml	in 1875 ml	in 2500 ml
Energy in the form of lipids [kJ (kcal)]	1590 (380)	995 (240)	1990 (475)	2985 (715)	3980 (950)
Energy in the form of carbohydrates [kJ (kcal)]	2415 (575)	1510 (360)	3015 (720)	4520 (1080)	6030 (1440)
Energy in the form of amino acids [kJ (kcal)]	940 (225)	585 (140)	1170 (280)	1755 (420)	2340 (560)
Non-protein energy [kJ (kcal)]	4005 (955)	2505 (600)	5005 (1195)	7510 (1795)	10010 (2390)
Total energy [kJ (kcal)]	4945 (1180)	3090 (740)	6175 (1475)	9260 (2215)	12350 (2950)

Osmolality [mOsm/kg]	2170
Theoretical osmolality [mOsm/l]	1545
pH	5.0 - 6.0

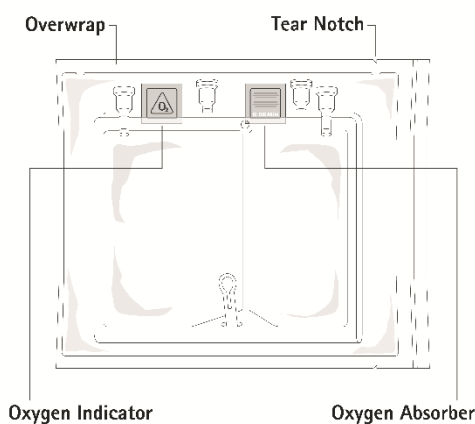
The other ingredients are citric acid monohydrate (for pH adjustment), glycerol, egg lecithin, sodium oleate, sodium hydroxide (for pH adjustment), all-rac-alpha-Tocopherol and water for injections.

What Nutriflex Omega 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.

Nutriflex Omega 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)
- 2500 ml (1000 ml of amino acids solution + 500 ml of fat emulsion + 1000 ml of glucose solution)



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

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.

The two upper chambers can be connected with the lower chamber by opening the intermediate seam.

The different container sizes are presented in cartons containing five bags.

Pack sizes: 5 x 625 ml, 5 x 1250 ml, 5 x 1875 ml and 5 x 2500 ml

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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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 seam 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 discoloration or signs of phase separation (oil drops, oil layer). Stop the infusion immediately in case of discoloration of the emulsion or signs of phase separation.

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

Preparation of the mixed emulsion:

Remove the bag from its protective overwrap and proceed as follows:

- Put the bag on a solid, flat surface
- Mix glucose with amino acids by pressing the upper left chamber against the peel seam, then add the fat emulsion by pressing the upper right chamber against the peel seam
- Mix the contents of the bag thoroughly.

The mixture is a milky white homogenous oil-in-water emulsion.

Preparation for infusion:

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

- Fold the bag and hang it on the infusion stand by the centre hanging loop
- Remove the protective cap from the infusion port 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.

If filters are used they must be lipid-permeable (pore size = 1.2 µm).

Shelf life after removing the protective overwrap and after mixing of the 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.

Nutriflex Omega special must not be mixed with other medicinal products for which compatibility has not been documented.

Nutriflex Omega special should not be given simultaneously with blood in the same infusion set due to the risk of pseudoagglutination.