PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

NUTRIFLEX OMEGA SPECIALIZED

Emulsion for infusion

Read all of this leaflet carefully before you are given NUTRIFLEX OMEGA SPECIALIZED

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- NUTRIFLEX OMEGA SPECIALIZED has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet:

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

1. What NUTRIFLEX OMEGA SPECIALIZED is and what it is used for

NUTRIFLEX OMEGA SPECIALIZED 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.

NUTRIFLEX OMEGA SPECIALIZED is given to adults.

You are given NUTRIFLEX OMEGA SPECIALIZED 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.

2. What you need to know before you take NUTRIFLEX OMEGA SPECIALIZED

NUTRIFLEX OMEGA SPECIALIZED should not be administered to you:

if you are hypersensitive (allergic) to any of the active ingredients or any of the other ingredients of NUTRIFLEX OMEGA SPECIALIZED (listed in section 6).

if you are allergic to egg, peanut, soyabean or fish.

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

Also do not use NUTRIFLEX OMEGA SPECIALIZED 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 where no dialysis facilities are available
- disturbances of your body salt composition
- fluid deficit or excess water in your body
- water in 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

Take special care with NUTRIFLEX OMEGA SPECIALIZED 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
- your blood clotting function is impaired or if your vitamin K level might be too low.

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 healthcare professional may also take measures to ensure that your body's fluid and electrolyte requirements are met. In addition to NUTRIFLEX OMEGA SPECIALIZED you may receive further nutrients (foodstuffs) in order to fully recover your requirements.

Children and adolescents

The safety and efficacy in children over 2 years 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 SPECIALIZED:

Always tell your healthcare professional if you are taking any other medicine (this includes complementary or traditional medicines).

NUTRIFLEX OMEGA SPECIALIZED 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 or heart problems (ACE-inhibitors and angiotensin-II-receptor antagonists)
- medicines used in organ transplants such cyclosporin and tacrolimus
- medicines to treat inflammation (corticosteroids)
- hormone preparations that affect your fluid balance (adrenocorticotropic hormone [ACTH]).

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider 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 SPECIALIZED in pregnant women.
Breastfeeding is not recommended for mothers on parenteral nutrition.

Driving and using machines

NUTRIFLEX OMEGA SPECIALIZED is normally given to immobile patients in a hospital or clinic. This will exclude driving and using machines. However, the medicine itself has no effect on the ability to drive and use machines.
If you have further questions on the use of this product, ask your doctor or pharmacist.

NUTRIFLEX OMEGA SPECIALIZED 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.

Thus, this medicine provides sufficient amounts of sodium in good agreement with the sodium recommendation for parenteral nutrition.

3. How to take NUTRIFLEX OMEGA SPECIALIZED

Your doctor will tell you how long your treatment with NUTRIFLEX OMEGA SPECIALIZED will last.

If you have the impression that the effect of NUTRIFLEX OMEGA SPECIALIZED is too strong or too weak, tell your doctor or pharmacist.

You will not be expected to give yourself NUTRIFLEX OMEGA SPECIALIZED. It will be given to you by a person who is qualified to do so.

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

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

The safety and efficacy in children over 2 years have not been established. This medicine must not be given to newborn infants, infants and toddlers under two years old.

If you use more NUTRIFLEX OMEGA SPECIALIZED than you should

Since a health care provider will administer NUTRIFLEX OMEGA SPECIALIZED, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

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 in 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 of loss of consciousness due to extremely high blood sugar
- enlargement of the liver (hepatomegaly) with and 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 (leukopenia)
- reduction of blood platelet count (thrombocytopenia)
- increase of immature red blood cells (reticulocytosis)
- rupture of blood cells (haemolysis)
- bleeding or a tendency to bleed
- 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.

If you forget to use NUTRIFLEX OMEGA SPECIALIZED

Since a health care provider will administer NUTRIFLEX OMEGA SPECIALIZED, it is unlikely that the dose will be missed.

4. Possible side effects

NUTRIFLEX OMEGA SPECIALIZED can have side effects.

Not all side effects reported for NUTRIFLEX OMEGA SPECIALIZED are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking NUTRIFLEX OMEGA SPECIALIZED, please consult your doctor, pharmacist or other healthcare professional for advice.

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:

Less frequent side effects:

- allergic reactions, for example skin reactions, shortness of breath, swelling of the lips, mouth and throat, difficult breathing
- feeling sick, vomiting, loss of appetite
- 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
- 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 SPECIALIZED than you should” in section 3. Symptoms normally disappear when the infusion is stopped.

Frequency not known:

- reduction of white blood cell count (leucopenia)
- reduction of blood platelet count (thrombocytopenia)
- impaired bile flow (cholestasis).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get 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 via https://primaryreporting.who-umc.org/ZA. By reporting side effects, you can help provide more information on the safety of NUTRIFLEX OMEGA SPECIALIZED.

5. How to store NUTRIFLEX OMEGA SPECIALIZED

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Store at or below 25 °C.

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

Do not use this medicine after the expiry date which is stated on the label. The expiry date refers to the last date of that month.

Keep the bags in the overwrap in order to protect from light.

6. Contents of the pack and other information

What NUTRIFLEX OMEGA SPECIALIZED 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**
Medium-chain triglycerides	20,00 g	12,50 g	25,00 g	37,50 g
Soya-bean oil, refined	16,00 g	10,00 g	20,00 g	30,00 g
Omega-3-acid triglycerides	4,000 g	2,500 g	5,000 g	7,500 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 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
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 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
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

Electrolyte (mmol)	**In 1000 mL**	**In 625 mL**	**In 1250 mL**	**In 1875 mL**
Sodium	53,6	33,5	67	100,5
Potassium	37,6	23,5	47	70,5
Magnesium	4,2	2,65	5,3	7,95
Calcium	4,2	2,65	5,3	7,95
Zinc	0,03	0,02	0,04	0,06
Chloride	48	30	60	90
Acetate	48	30	60	90

Phosphate	16	10	20	30

Amino acid content (g)	56,0	35,0	70,1	105,1
Nitrogen content (g)	8	5	10	15
Carbohydrate content (g)	144	90	180	270
Lipid content (g)	40	25	50	75

Energy in the form of lipids [kJ (kcal)]	1590 (380)	995 (240)	1990 (475)	2985 (715)
Energy in the form of carbohydrates [kJ (kcal)]	2415 (575)	1510 (360)	3015 (720)	4520 (1080)
Energy in the form of amino acids [kJ (kcal)]	940 (225)	585 (140)	1170 (280)	1755 (420)
Non-protein energy [kJ (kcal)]	4005 (955)	2505 (600)	5005 (1195)	7510 (1795)
Total energy [kJ (kcal)]	4945 (1180)	3090 (740)	6175 (1475)	9260 (2215)

Osmolality [mOsm/kg]	2115
Theoretical osmolarity [mOsm/L]	1545
pH	5,0 – 6,0

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

What NUTRIFLEX OMEGA SPECIALIZED 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 SPECIALIZED is supplied in flexible multi-chamber 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)

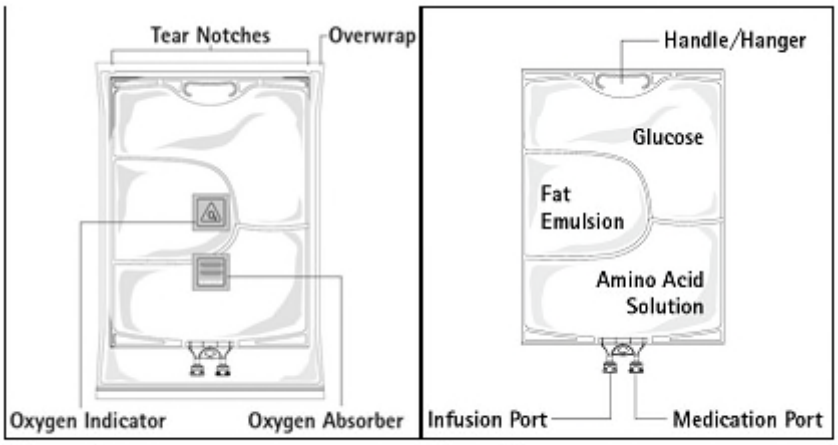


Figure A Figure B

Figure A: The multi-chamber 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 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 seam results in sterile mixing to form an emulsion.

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

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.

HOLDER OF THE CERTIFICATE OF REGISTRATION

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