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PACKAGE LEAFLET: INFORMATION FOR THE USER

B. Braun Melsungen AG · 34209 Melsungen, Germany

Nutriflex® peri Solution for Infusion

Amino acids / Glucose / Electrolytes

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, please ask your healthcare professional.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects, talk to your healthcare professional. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Nutriflex peri is and what it is used for

The product contains substances (nutrients) called amino acids, salts (electrolytes) and glucose which are essential for the body to grow or to recover and calories in the form of carbohydrates.
You are given this product by a vein drip (infusion) because you are unable to eat adequately or cannot be fed via a tube. It is called a nutritional supplement.
Nutriflex peri can be also used via a small vein (peripheral venous catheter) when administration via a large vein (central venous catheter) is not possible.

2. What you need to know before you use Nutriflex peri

Do not use Nutriflex peri
- if you are allergic (hypersensitive) to active substances or any of the other ingredients of Nutriflex peri
- if you have severe inborn disorder of amino acid metabolism, where you need a special protein diet
- if you have any kind of poorly controlled metabolic disorder, for example severe diabetes mellitus, accumulation of sour (acidic) substances in your blood (acidosis) or inadequate supply of oxygen to cells (hypoxia)
- if you have excessively high blood sugar level that needs more than 6 units of insulin per hour to be controlled
- if you have abnormally high blood electrolyte levels
- if you have bleeding within the skull or the spinal cord.

Nutriflex peri should not be given to babies and infants that are under two years old.

As with other medicines of this type Nutriflex peri should not be given if you have:
- severe liver disease
- severe kidney disease without treatment by artificial kidney
- life threatening blood circulation problems as can occur if you are in a state of collapse or shock
- heart problems (decompensated cardiac insufficiency).

Warnings and precautions
Talk to your healthcare professional before using Nutriflex peri
- if you have impaired heart or kidney function
- if you have disturbances in fluid, electrolyte or acid-base balance, for example low body water and salt content (hypotonic dehydration), low sodium or potassium level in your blood
- if you have high blood glucose levels.

Special care will be taken to adjust and control your daily dose if you have impairment of kidneys, liver, adrenal glands, heart or lungs or if you have altered amino acid metabolism.
If you are in a state of severe underfeeding, special care will be taken to build up your intravenous feeding gradually.
Nutriflex peri contains glucose (a sugar) so this may affect your blood sugar level. Blood samples may have to be taken to check this.
Moreover other tests may be performed in order to ensure that your fluid levels, electrolytes, and acid-base balance are correct. For longer administration times, some tests on your blood as well as kidney and liver function will be done as well.
Special precautions will be taken when you receive this medicine to ensure that the product remains sterile.

Other medicines and Nutriflex peri
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.
Nutriflex peri can interact with some other medicines. Please tell your doctor if you are taking any of the following:
- medicines for treatment of inflammation (corticosteroids)
- hormone preparations affecting your fluid balance ('ACTH')
- medicines that promote urine flow such as triamterene or amiloride
- medicines for treatment of high-blood pressure (ACE-inhibitors)
- medicines used in transplant medicine such as cyclosporine and tacrolimus.

Pregnancy, breast-feeding and fertility
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.

Pregnancy
If you are pregnant, you will receive this medicine only if the doctor considers it absolutely necessary for your recovery.

Breast-feeding
Breast-feeding is not recommended during treatment with this medicine.

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

3. How to use Nutriflex peri

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

Adults
The daily dose for this age group is up to 40 ml of solution for infusion per kg body weight (BW) per day. This solution will be administered to you at a maximum rate of 2 ml per kg BW per hour.

Patients with kidney or liver impairment
The doses will be adjusted according to your individual requirements if you have a liver or kidney disease.

Route of administration
Nutriflex peri will be administered to you by infusion into a vein. It can be infused into smaller veins (peripheral veins).

If you receive more Nutriflex peri than you should
If you think that you have been given an overdose, please talk to a doctor or pharmacist immediately.

If you are given too much of this medicine this may lead to symptoms including:
- swelling caused by excess body fluid
- changes in your blood, which can be measured in a blood test
- sickness, vomiting, shivering
- high blood sugar level and glucose in urine
- dehydration
- unconsciousness caused by extremely high blood glucose levels.

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

4. Possible side effects

Like all medicines, Nutriflex peri can cause side effects, although not everybody gets them.
Side effects are mainly caused by overdose or too rapid infusion. They will usually disappear when the infusion is stopped.

If you experience any of the following side effects, contact your doctor or hospital immediately

Not known (frequency cannot be estimated from the available data)
- Reactions of intolerance (re-feeding syndrome) may occur if you are in a state of severe underfeeding and too high doses are administered. (The symptoms of these intolerance reactions are drops of serum electrolyte levels, sleepiness and damage to red blood cells.
- Feeling sick (nausea) and vomiting
- Excessive amounts of urine: If the solution is infused too rapidly, you may pass excessive amounts of urine.

Abnormal results of liver function tests and disturbance of bile flux (cholestasis) have been reported in some patients receiving intravenous (infusion through a vein) nutrition.
If these rare side effects occur your treatment should be stopped, or if the doctor decides, it may be continued but at a lower dose level.

Not known (frequency cannot be estimated from the available data)
- If your treatment is stopped abruptly, your blood sugar level may drop below normal levels with symptoms such as e.g. feeling of extreme hunger, dizziness, blurry vision, trembling or shakiness, headache and sweating, especially in children under 3 years, patients having diabetes or having other problems with glucose tolerance.
- Vein irritation or inflammation of the wall of a vein at the site of infusion may occur a few days after starting your treatment.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects
If you get any side effects, talk to your healthcare professional. 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.

5. How to store Nutriflex peri

Keep this medicine out of the sight and reach of children.
Do not store above 25°C.
Keep bag in the outer carton in order to protect from light.
Do not use Nutriflex peri after the expiry date which is stated on the bag printing and on the carton label. The expiry date refers to the last day of that month.
Only use Nutriflex peri if the solution is clear and the bag undamaged. After infusion, any remaining solution should never be stored for later use.

6. Contents of the pack and other information

What Nutriflex peri contains
- The active substances are amino acids, glucose and electrolytes.

Each bag contains after mixing:

	1000 ml	2000 ml
Isoleucine	2.34 g	4.68 g
Leucine	3.13 g	6.26 g
Lysine hydrochloride	2.84 g	5.68 g
equivalent to lysine	2.27 g	4.54 g
Methionine	1.96 g	3.92 g
Phenylalanine	3.51 g	7.02 g
Threonine	1.82 g	3.64 g
Tryptophan	0.57 g	1.14 g
Valine	2.60 g	5.20 g
Arginine monoglutamate	4.98 g	9.96 g
equivalent to arginine	2.70 g	5.40 g
equivalent to glutamic acid	2.28 g	4.56 g
Histidine hydrochloride monohydrate	1.69 g	3.38 g
equivalent to histidine	1.25 g	2.50 g
Alanine	4.85 g	9.70 g
Aspartic acid	1.50 g	3.00 g
Glutamic acid	1.22 g	2.44 g
Glycine	1.65 g	3.30 g
Proline	3.40 g	6.80 g
Serine	3.00 g	6.00 g
Magnesium acetate tetrahydrate	0.86 g	1.72 g
Sodium acetate trihydrate	1.56 g	3.12 g
Potassium dihydrogen phosphate	0.78 g	1.56 g
Potassium hydroxide	0.52 g	1.04 g
Sodium hydroxide	0.50 g	1.00 g
Glucose monohydrate	88.0 g	176.0 g
equivalent to glucose	80.0 g	160.0 g
Sodium chloride	0.17 g	0.34 g
Calcium chloride dihydrate	0.37 g	0.74 g

- The other ingredients are citric acid monohydrate and water for injections.

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Electrolytes:	**1000 ml**	**2000 ml**
Sodium	27.0 mmol	54.0 mmol
Potassium	15.0 mmol	30.0 mmol
Calcium	2.5 mmol	5.0 mmol
Magnesium	4.0 mmol	8.0 mmol
Chloride	31.6 mmol	63.2 mmol
Phosphate	5.7 mmol	11.4 mmol
Acetate	19.5 mmol	39.0 mmol
	1000 ml	**2000 ml**
Amino acid content	40 g	80 g
Nitrogen content	5.7 g	11.4 g
Carbohydrate content	80 g	160 g
	1000 ml	**2000 ml**
Non-protein energy [kJ (kcal)]	1340 (320)	2680 (640)
Total energy [kJ (kcal)]	2010 (480)	4020 (960)
Osmolarity	900 mOsm/l	900 mOsm/l
pH	4.8 – 6.0	4.8 – 6.0

What Nutriflex peri looks like and contents of the pack

Nutriflex peri is presented in an infusion bag with two compartments. The lower compartment contains glucose while the upper compartment contains the amino acid solution. The glucose and the amino acid solution are clear, colourless or faintly straw-coloured.

The product is supplied in two-chamber plastic bags containing:
- 1000 ml (400 ml of amino acids solution + 600 ml of glucose solution)
- 2000 ml (800 ml of amino acids solution + 1200 ml of glucose solution)

Pack sizes: 5 × 1000 ml, 5 × 2000 ml

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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THE FOLLOWING INFORMATION IS INTENDED FOR MEDICAL OR HEALTHCARE PROFESSIONALS ONLY:

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

Preparation of the mixed solution:
Immediately before use the internal peel seam between the two compartments must be opened allowing the respective contents to be aseptically mixed.

Remove the bag from its protective bag and proceed as follows:
- Open out the bag and lay on a solid surface
- Open the peel seam by using pressure with both hands
- Briefly mix the contents of the bag together.

An additive port is provided for admixing of supplements to Nutriflex peri. When admixing other solutions or fat emulsions to Nutriflex peri, aseptic precautions must be strictly observed. Fat emulsions can be easily admixed by means of a special transfer set.

Storage after mixing of the contents

Ideally after mixing the two solutions, Nutriflex peri should be administered immediately but in special circumstances it can be stored for up to 7 days at room temperature and up to 14 days if stored in a refrigerator (including administration time). Partially used containers must not be stored for later use.

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