PACKAGE LEAFLET: INFORMATION FOR THE USER

Nutriflex plus 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 further questions, 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 signs of illness 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 plus is and what it is used for

The product contains substances (nutrients) called amino acids, salts (electrolytes) and carbohydrates (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.

Nutriflex plus is specifically indicated for adults and children aged 2-17 years with moderately severe catabolism, a condition where patients are burning up their stores of energy, protein, etc. faster than they can be replaced.

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

Do not use Nutriflex plus
- if you are allergic to the active substances or any of the other ingredients of this medicine (listed in section 6)
- if you have an inborn error of amino acid metabolism, where you need a special protein diet
- if you have abnormally high blood sugar levels that need more than 6 units of insulin per hour to be controlled
- if you have abnormally high levels of acidic substances in the blood (acidosis)
- if you have bleeding within the skull or the spinal cord
- if you have severe liver failure (severe hepatic insufficiency)
- if you have severe kidney failure (severe renal insufficiency) without access to treatment with an artificial kidney (haemofiltration or dialysis)

As with other medicines of this type Nutriflex plus should not be given if you have:

- acute phase of heart attack (myocardial infarction) or stroke
- any kind of poorly controlled metabolic disorder, for example state of unconsciousness (coma), the cause of which is not known or insufficient supply of oxygen to tissues or decompensated diabetes mellitus
- life-threatening blood circulation problems such as those that can occur for example if you are in a state of collapse or shock, have accumulation of fluid in your lungs (pulmonary oedema) or your water balance is disturbed

Nutriflex plus must not be given to newborn infants, infants and toddlers that are under two years old.

Warnings and precautions

Talk to your healthcare professional before using Nutriflex plus

- if you have impaired heart or kidney function
- if you have disturbances in fluid, salt or acid-base balance, for example low body fluid and salt content (hypotonic dehydration) or low sodium or potassium levels in your blood
- if you have abnormally high blood sugar 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.

Your doctor will also take special care for you if your blood-brain barrier is damaged, because then this medicine may cause an increase of the pressure within your skull or the spinal cord.

If you are in a state of severe underfeeding, special care will be taken to build up your intravenous feeding gradually, accompanied by adequate controls and necessary supplies of electrolytes, in particular potassium, magnesium and phosphate.

This medicine contains glucose (a sugar) so this may affect your blood sugar level. Blood samples may have to be taken to check this.

If your infusion has accidentally been stopped suddenly, your blood sugar level may also drop suddenly. Your doctor will take this into consideration especially when your ability to metabolise glucose is impaired (e.g. if you have diabetes) or when children below the age of 3 receive this solution. Therefore especially after stopping the infusion your blood sugar level will be carefully monitored.

Moreover controls of your blood salt levels, the water balance, the acid-base balance and of blood cell counts, blood clotting, kidney and liver function are necessary.

The doctor will also take measures to ensure that your body's fluid and electrolyte requirements are met. In addition to Nutriflex plus you will receive further nutrients (foodstuffs) in order to fully cover your requirements.

As with all intravenous solutions strict aseptic precautions are necessary for the infusion of Nutriflex plus.

Children and adolescents

Concerning sudden drop of the blood sugar level of your child after accidental stop of the infusion, please refer also to section 'Warnings and precautions' above.

Your doctor will not give Nutriflex plus to children under two years old.

Other medicines and Nutriflex plus

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

Nutriflex plus can interact with some other medicines. Please tell your doctor if you are taking or receiving any of the following:
- medicines to treat inflammation (corticosteroids)
- hormone preparations that affect your fluid balance (adrenocorticotropic hormone [ACTH])
- medicines to promote urine flow (diuretics) such as spironolactone, triamterene or amiloride
- medicines to treat high blood pressure (ACE inhibitors) such as captopril and enalapril
- medicines to treat high blood pressure or heart problems (angiotensin-II-receptor antagonists) such as losartan and valsartan
- medicines used in organ transplants 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 if women need intravenous feeding in that time.

Fertility
No data available.

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 plus

This medicine will be administered to you by intravenous infusion (drip), that is, through a small tube directly into a large vein.

Before infusion the solution must always be brought to room temperature.

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

The recommended daily dose for adults is up to 40 ml solution for infusion per kg body weight. Your doctor will determine the exact dose.

Use in children and adolescents
There are special dosage guidelines for children and adolescents between 2 and 17 years old. Your doctor knows this guidelines and will determine the dose accordingly.

If you received more Nutriflex plus than you should

It is unlikely that you would receive an overdose of this medicine on proper administration. However, if you are given too much of this medicine this may lead to:
- abnormally high body fluid levels (hyperhydration)
- abnormally high amounts of urine (polyuria)
- disorders of your body salt composition (electrolyte imbalance)

- water on your lungs (pulmonary oedema)
- loss of amino acids through the urine and disturbed amino acid balance
- accumulation of acidic substances in your blood (metabolic acidosis)
- feeling sick, vomiting, shivering, headache
- high levels of nitrogen in the blood (hyperammonaemia)
- abnormally high blood sugar levels (hyperglycaemia)
- glucose in the urine (glucosuria)
- fluid deficit (dehydration)
- blood much more concentrated than normal (hyperosmolality)
- unconsciousness caused by extremely high blood sugar levels (hyperglycaemic-hyperosmolar coma).

If any of these symptoms occur, the infusion will be stopped immediately. Your doctor will decide on any additional treatment to be given. The infusion will not be started again until you have recovered.

If you have any further questions on the use of this medicine, ask your healthcare professional.

4. Possible side effects

Like all medicines, this medicine 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.

Rare (may affect up to 1 in 1,000 people)
- Feeling sick (nausea), vomiting and decreased appetite

If these side effects occur, your treatment should be stopped, or if the doctor decides, it may be continued but at a lower dose level.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.
You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; e-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Nutriflex plus

Keep this medicine out of the sight and reach of children.
Do not store above 25 °C.
Keep the bag in the outer carton 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 Nutriflex plus contains

- The active substances are amino acids, glucose and electrolytes.

Each bag contains after mixing:

	1000 ml	**2000 ml**
Isoleucine	2.82 g	5.64 g
Leucine	3.76 g	7.52 g
Lysine hydrochloride equivalent to lysine	3.41 g 2.73 g	6.82 g 5.46 g
Methionine	2.35 g	4.70 g
Phenylalanine	4.21 g	8.42 g
Threonine	2.18 g	4.36 g
Tryptophan	0.68 g	1.36 g
Valine	3.12 g	6.24 g
Arginine monoglutamate equivalent to arginine equivalent to glutamic acid	5.98 g 3.24 g 2.74 g	11.96 g 6.48 g 5.48 g
Histidine hydrochloride monohydrate equivalent to histidine	2.03 g 1.50 g	4.06 g 3.00 g
Alanine	5.82 g	11.64 g
Aspartic acid	1.80 g	3.60 g
Glutamic acid	1.47 g	2.94 g
Glycine	1.98 g	3.96 g
Proline	4.08 g	8.16 g
Serine	3.60 g	7.20 g
Magnesium acetate tetrahydrate	1.23 g	2.46 g
Sodium acetate trihydrate	1.56 g	3.12 g
Sodium dihydrogen phosphate dihydrate	3.12 g	6.24 g
Potassium hydroxide	1.40 g	2.80 g
Sodium hydroxide	0.23 g	0.46 g
Glucose monohydrate equivalent to glucose	165.0 g 150.0 g	330.0 g 300.0 g
Calcium chloride dihydrate	0.53 g	1.06 g

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

Electrolytes:	**1000 ml**	**2000 ml**
Sodium	37.2 mmol	74.4 mmol
Potassium	25.0 mmol	50.0 mmol
Calcium	3.6 mmol	7.2 mmol
Magnesium	5.7 mmol	11.4 mmol
Chloride	35.5 mmol	71.0 mmol
Phosphate	20.0 mmol	40.0 mmol
Acetate	22.9 mmol	45.8 mmol

	1000 ml	**2000 ml**
Amino acid content	48 g	96 g
Nitrogen content	6.8 g	13.6 g
Carbohydrate content	150 g	300 g

	1000 ml	**2000 ml**
Energy in the form of amino acids [kJ (kcal)]	803 (192)	1607 (384)
Energy in the form of carbohydrates [kJ (kcal)]	2510 (600)	5021 (1200)
Total energy [kJ (kcal)]	3313 (792)	6628 (1584)

Theoretical osmolarity [mOsm/l]	1400	1400
pH	4.8 – 6.0	4.8 – 6.0

What Nutriflex plus looks like and contents of the pack

This medicine is a solution for infusion, i.e. it is administered through a small tube into a vein.

Nutriflex plus 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 solutions are clear and colourless or slightly yellowish.

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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This leaflet was last revised in 03.2017.

The following information is intended for healthcare professionals only:

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

Only use Nutriflex plus if the solution is clear and the bag undamaged. After infusion, any remaining solution should never be stored for later use.

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 plus.

When admixing other solutions or fat emulsions to Nutriflex plus, aseptic precautions must be strictly observed. Fat emulsions can be easily admixed by means of a special transfer set.

Maximum infusion rates:
The maximum infusion rate for adults, children and adolescents from 2 to 17 years is 1.6 ml per kg body weight per hour.

Storage after mixing of the contents
Ideally after mixing the two solutions, Nutriflex plus should be administered immediately but if immediate administration is not possible 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 at 2 – 8°C (including administration time). Partially used containers must not be stored for later use.