Patient Information Leaflet

SCHEDULING STATUS: S3

NUTRIFLEX® LIPID PERI (Intravenous infusion)

Read all of this leaflet carefully before you are given NUTRIFLEX® LIPID PERI.

- Keep this leaflet. You may need to read it again.
- If you have further questions, ask your doctor, pharmacist, ~~or~~ nurse or other healthcare provider.

What is in this leaflet

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

1. What is Nutriflex® Lipid Peri is and what it is used for

Nutriflex® Lipid Peri supplies an adequate balanced diet to patients who cannot eat. It supplies the patients with energy (carbohydrates), essential fatty acids, nitrogen, amino acids, electrolytes and fluids, which are administered directly into a vein.

2. What you need to know before you are given Nutriflex® Lipid Peri

Do not use Nutriflex® Lipid Peri

- If you are hypersensitive (allergic) to any of the active substances, to egg, peanut or soybean or any of the other ingredients of Nutriflex® Lipid Peri (listed in section 6).

- Nutriflex® Lipid Peri must not be given to newborn infants, infants and toddlers under two years

old.

- Unstable blood circulation problems.

- Heart attacks or strokes.

- 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 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

  – 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® Lipid Peri.

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® Lipid Peri you may receive further nutrients (foodstuffs) in order to fully cover your requirements.

***Nutriflex® Lipid Peri** contains sodium*

This medicinal product contains 1150 mg sodium per 1250 mL bag, equivalent to 58 % of the WHO recommended maximum daily intake of 2 g sodium for an adult.

The maximum daily dose of this product for a 70 kg adult is equivalent to 129 % of the WHO recommended maximum daily intake for sodium.

Nutriflex® Lipid Peri is considered high in sodium. This should be particularly taken into account for those on a low salt diet.

Other medicines and Nutriflex® Lipid Peri

Always tell your health care provider if you are taking other medicines (This includes all complimentary or traditional medicines).

Nutriflex® Lipid Peri 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 (adrenocorticotropic hormone or 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.

The safe use of Nutriflex® Lipid Peri during pregnancy and breastfeeding has not been established.

Breast feeding is not recommended for mothers on parenteral nutrition.

Driving and using machines

Nutriflex® Lipid Peri 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.

3. How to use NUTRIFLEX® LIPID PERI

Do not share medicines prescribed for you with any other person.

Always use Nutriflex® Lipid Peri exactly as your doctor has told you. Check with your doctor if you are unsure.

Nutriflex® Lipid Peri will be given via an intravenous infusion (drip), that is, through a small tube directly into a vein. Your doctor will decide how much of this medicine you need and for how long you will require treatment with Nutriflex® Lipid Peri.

If you use more Nutriflex® Lipid Peri 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.

Since a health care provider will administer Nutriflex® Lipid Peri, he / she will control the dosage.

However, in the event of overdosage your doctor will manage the overdosage.

If you forget to use Nutriflex® Lipid Peri

Since a health care provider will administer Nutriflex® Lipid Peri, it is unlikely that the dose will be missed.

4. Possible side effects

Nutriflex® Lipid Peri can have side effects.

Not all side effects reported for Nutriflex® Lipid Peri are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Nutriflex® Lipid Peri, please consult your health care professional for advice.

If any of the following happens, stop using Nutriflex® Lipid Peri and tell your doctor immediately:

- Skin reactions such as rashes
- Shortness of breath and difficulty breathing
- Swelling of the lips, mouth and throat

These are all very serious side effects. If you have them, you may have had a serious reaction to Nutriflex® Lipid Peri. You may need urgent medical attention or hospitalisation.

The following side effects may occur:

Frequent side-effects:

- Irritation or inflammation of veins (phlebitis, thrombophlebitis)

Less frequent side-effects:

- 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® Lipid Peri than you should” in section 3. Symptoms normally disappear when the infusion is stopped.
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Side-effects where frequency is unknown

- Low blood potassium and/or phosphate levels
- High or low blood magnesium levels
- Reduction of white blood cell count (leucopenia)
- Reduction of blood platelet count (thrombocytopenia)
- Impaired bile flow (cholestasis)
- Difficulty breathing

Reporting of side effects

If you get side effects, talk to your doctor or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of Nutriflex® Lipid Peri.

5. How to store Nutriflex® Lipid Peri

Protect from light and store at or below 25 °C.

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

The emulsion is to be used immediately after mixing. It can be stored for 7 days at 2 – 8 °C and for 48 hours at 25 °C.

Do not use after the expiry date printed on the label of the container.

All medicines should be safely disposed of. Return all unused medicine to the pharmacy for disposal.

KEEP OUT OF REACH AND SIGHT OF CHILDREN

6. Contents of the pack and other information

What Nutriflex® Lipid Peri contains

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

glucose, sodium dihydrogen phosphate dihydrate, zinc acetate dihydrate, soybean oil, medium-chain triglycerides, isoleucine, leucine, lysine hydrochloride, methionine, phenylalanine, threonine, tryptophan, valine, arginine, histidine hydrochloride monohydrate, alanine, aspartic acid, glutamic acid, glycine, proline, serine, sodium hydroxide, sodium chloride, sodium acetate trihydrate, potassium acetate, magnesium acetate tetrahydrate, and calcium chloride dihydrate.

The other ingredients are citric acid monohydrate (for pH adjustment), egg lecithin, glycerol, sodium oleate and water for injections.

What Nutriflex® Lipid Peri looks like and contents of the pack

Nutriflex® Lipid Peri is available in a multichamber bag. The upper left-hand chamber contains a glucose solution, the upper right-hand chamber contains a fat emulsion, and the lower chamber contains an amino acid solution.

Amino acid chamber: Clear, colourless up to faintly straw coloured solution, practically free from particles.

Glucose chamber: Clear, colourless up to faintly straw coloured solution, practically free from particles.

Fat emulsion chamber: A white, milky oil-in-water emulsion.

Nutriflex® Lipid Peri will be manufactured as a transparent colourless three chamber bag. The two upper compartments of this bag are connected with the lower compartment by peel seams. The bag is made of a co-extruded film of Polyamide 11 and Polypropylene (V90 film) and is available in pack sizes of 5 x 1250 mL, 5 x 1875 mL and 5 x 2500 mL packed in a carton.

Not all pack sizes may be marketed.

Holder of certificate of registration

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