1.3.2.1 Approved Patient Information Leaflet

SCHEDULING STATUS: S3

PATIENT INFORMATION LEAFLET

NUTRIFLEX® OMEGA PERI

(Emulsion for infusion)

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

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

What is in this leaflet

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

1. What NUTRIFLEX® OMEGA PERI is and what it is used for

Nutriflex® Omega Peri 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 Peri** 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.

Nutriflex® Omega Peri is for use in adults.

2. What you need to know before you are given NUTRIFLEX® OMEGA PERI

Nutriflex® Omega Peri should not be administered to you:

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

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

Also do not use **Nutriflex® Omega Peri** 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.
- Severe high cholesterol level, specifically where triglycerides are ≥ 1000 mg/dL or 11,4 mmol/L)
- 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 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 or health care provider before being given **Nutriflex Omega 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.
- 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 health care professionals may also take measures to ensure that your body's fluid and

electrolyte requirements are met. In addition to **Nutriflex® Omega Peri** 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 PERI

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

Nutriflex® Omega 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.

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 Peri** in pregnant women.

Breast feeding is not recommended for mothers on parenteral nutrition.

Driving and using machines

Nutriflex® Omega Peri is normally given to immobile patients in a hospital or clinic. This will exclude driving or using machines. However, this medicine has no effect on the ability to drive and use machines.

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

3. How to take NUTRIFLEX® OMEGA PERI

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

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

Your doctor will decide how much of this medicine you need and for how long you will require treatment with **Nutriflex® Omega Peri**.

You will not be expected to give yourself **Nutriflex® Omega Peri**. It will be given to you by a person who is qualified to do so.

Nutriflex® Omega Peri will be given via an intravenous infusion (drip), that is, through a small tube directly into a large vein.

Use in 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.

If you use more NUTRIFLEX® OMEGA PERI than you should

Since a health care provider will administer **Nutriflex® Omega Peri** 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 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.

If you forget to take NUTRIFLEX® OMEGA PERI

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

4. Possible side effects

Nutriflex® Omega Peri can have side effects.

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

If any of the following happens, stop using **Nutriflex® Omega 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® Omega 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® Omega Peri** than you should” in section 3. Symptoms normally disappear when the infusion is stopped.

Side-effects where frequency is unknown

- Reduction of white blood cell count (leucopenia)
- Reduction of blood platelet count (thrombocytopenia)
- Low levels of potassium in the blood (hypokalaemia)
- Low levels of phosphate in the blood (hypophosphataemia)
- Low levels of magnesium in the blood (hypomagnesaemia)
- 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 or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (whoumc.org) found on SAHPRA website.

By reporting side effects, you can help provide more information on the safety of **Nutriflex® Omega Peri**.

5. How to store NUTRIFLEX® OMEGA 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 to 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® Omega 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), glycerol, egg phospholipids for injection, sodium oleate, all-rac-α-tocopherol, sodium hydroxide (for pH adjustment) and water for injections.

What NUTRIFLEX® OMEGA PERI looks like and contents of the pack

Nutriflex® Omega Peri is supplied in flexible multi-chamber bags of multi-layer foil.

The inner layer in contact with the solution consists of polypropylene. The twin-base port is made of polypropylene and styrene ethylene butylene styrene. The multi-chamber bags contain:

- 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).
-

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 milky-white emulsion.

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

Pack sizes: 5 x 1250 ml; 5 x 1875 ml; 5 x 2500 ml.

Not all pack sizes may be marketed

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