Patient Information Leaflet

Please read this leaflet carefully before taking NUTRIFLEX® LIPID SPECIAL.

- **Keep this leaflet. You may need to read it again.**
- **If you have any further questions, please ask your doctor or your pharmacist.**
- **This medicine 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.**

SCHEDULING STATUS

S3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

NUTRIFLEX® LIPID SPECIAL (Intravenous infusion)

WHAT NUTRIFLEX® LIPID SPECIAL CONTAINS

The active substances are glucose, sodium dihydrogen phosphate, zinc acetate, soya-bean oil, medium chain triglycerides, isoleucine, leucine, lysine hydrochloride, methionine, phenylalanine, threonine, tryptophan, valine, arginine, histidine hydrochloride, alanine, aspartic acid, glutamic acid, glycine, proline, serine, sodium hydroxide, sodium chloride, sodium acetate.$3H_2O$, potassium acetate, magnesium acetate.$4H_2O$, calcium chloride.$2H_2O$, sodium, potassium, magnesium, calcium, zinc, chloride, acetate, phosphate.

The other ingredients are citric acid, egg lecithin, glycerol, sodium oleate and water for injection.

WHAT IS NUTRIFLEX® LIPID SPECIAL USED FOR

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

BEFORE RECEIVING NUTRIFLEX® LIPID SPECIAL

Do not take Nutriflex® Lipid Special:

- If you suffer from any metabolic disorder (fat, amino acid or carbohydrate).
- If you have any abnormal (high or low) levels of sodium, calcium, magnesium, potassium in your blood.
- If you have increased levels of glucose (sugar) in your blood.
- If you have a disturbed acid balance in your body.
- If you suffer from kidney or liver disorders.
- If you have a history of heart attacks or strokes.
- If you are allergic to egg or soy protein or to any of the ingredients.
- **Nutriflex® Lipid Special** should not be administered to children under the age of 2 years.

Using other medicines with Nutriflex® Lipid Special

If you are taking medicines on a regular basis, using the medicine at the same time with another medicine may cause undesirable interactions. Please consult your doctor, pharmacist or other health care professional for advice.

The following medication should be avoided when you are receiving **Nutriflex® Lipid Special**:

- Insulin
- Heparin and other blood thinning agents

The mixing of **Nutriflex® Lipid Special** with other intravenous medication is not recommended.

Pregnancy and breastfeeding:

If you are pregnant or breast feeding your baby while taking this medicine please consult your doctor, pharmacist or other health care professional for advice.

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

Breast feeding is not recommended while this product is used.

HOW NUTRIFLEX® LIPID SPECIAL WILL BE ADMINISTERED TO YOU

Nutriflex® Lipid Special will be given via an intravenous infusion. Your doctor will administer the correct quantity that is required for your situation.

POSSIBLE SIDE EFFECTS

Nutriflex® Lipid Special can cause side effects in some patients.
Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen after taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

The following side effects may occur:

Irritation at the injection site.

Back ache, pain in the chest, nausea, vomiting and flushing.

Slight increase in temperature; cold feeling; shivering; headache; loss of appetite; difficulty breathing; bone pain; fall or increase in blood pressure; allergic reactions; bluish discoloration of the skin due to reduced oxygen content of the blood.

STORAGE AND DISPOSAL INFORMATION

Protect from light and store 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 4 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

IDENTIFICATION OF NUTRIFLEX® LIPID SPECIAL

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.

PRESENTATION OF NUTRIFLEX® LIPID SPECIAL

Nutriflex® Lipid Special 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 1250 ml, 1875 ml and 2500 ml.

REGISTRATION NUMBER

41/25/0759

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

B Braun Medical (Pty) Ltd.

1055 Ridge Road

Laser Park

Honeydew

Tel. (011) 454 5000

DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET

10 December 2009