

# DATA SHEET

## NAME OF MEDICINE

STRUCTOLIPID 20% (64:36 ratio of long chain:medium chain triglycerides)  
Emulsion for Intravenous Infusion

## PRESENTATION

Structolipid is a white, homogenous emulsion and is designed for intravenous injection.

Sodium hydroxide is added to pH approximately 8. Structolipid has an energy content is 8.2 MJ (1960 kcal)/1000 mL and an osmolality of 350 mOsm/kg water.

## USES

### Actions

Purified structured triglyceride is an interesterified mixture of equimolar amounts of long chain triglycerides (LCT) and medium chain triglycerides (MCT), corresponding to 64% (w/w) and 36% (w/w), respectively. The fatty acids are randomly distributed within the interesterified triglyceride molecule. Purified structured triglyceride consists mainly of mixed chain triglycerides, i.e. containing medium as well as long chain fatty acids (approximately 75%) with minor proportions of LCT and MCT. MCT is a synthetic oil originated from coconut oil and/or palm kernel oil and LCT is added in the form of refined soya oil.

Structolipid is a fat emulsion with particle size and biological properties similar to those of endogenous chylomicrons.

Unlike chylomicrons, Structolipid does not contain cholesterol esters and apolipoproteins. Another difference compared with chylomicrons is that Structolipid is a mixture of long and medium chain fatty acids on the same glycerol molecule.

The emulsion provides both essential fatty acids (long chain fatty acids, LCFA) and energy substrate in the form of both LCFA and medium chain fatty acids (MCFA).

To prevent essential fatty acid deficiency, at least 20% of the nonprotein energy should be supplied in the form of fat emulsions with an adequate amount of linoleic and linolenic acid such as Structolipid.

### Pharmacokinetics

A study in healthy volunteers has shown that Structolipid is eliminated faster than emulsions containing only triglycerides with long chain fatty acids.

Retrospectively analysed data from studies in patients suggest a faster elimination of Structolipid than that of emulsions containing only LCT or a physical mixture of LCT and MCT.

Due to the metabolism of Structolipid, increased plasma levels of medium chain fatty acids, dicarboxylic acids and 3-hydroxy fatty acids will be generated. Studies in healthy volunteers have shown that the amounts of these metabolites are lower after infusion of Structolipid compared with after infusion of equimolar doses of fat in a

physical mixture of LCT and MCT. These metabolites were found to be completely eliminated in a blood sample drawn 16 hours after completion of the infusion. Dicarboxylic acids are excreted in the urine.

## **INDICATIONS**

Structolipid should be used to supply energy and essential fatty acids to adult patients as part of a parenteral nutrition regimen.

## **DOSAGE AND ADMINISTRATION**

The patient's ability to eliminate the fat infused, should govern the dosage and infusion rate, see "Precautions".

### Adults

The recommended dose is 1-1.5g triglycerides/kg body weight/day, corresponding to 5-7.5 mL/kg body weight/day, normally given over 10-24 hours.

The infusion rate should not exceed 0.75 mL/kg body weight/hour, corresponding to 0.15 g fat/body weight/hour.

### Children

Safety and efficacy in children have not been established.

### Administration

Structolipid should be administered by intravenous infusion as part of a parenteral nutrition regimen, including glucose, into a peripheral vein or via a central venous catheter.

## **CONTRAINDICATIONS**

- Hypersensitivity to egg-, soya- or peanut protein or to any of the other ingredients contained in Structolipid.
- Severe hyperlipaemia
- Severe liver insufficiency
- Haemophagocytotic syndrome
- Severe blood coagulation disorders
- Acute shock
- General contra-indications of an infusion therapy: acute pulmonary oedema  
Hyperhydration and decompensated cardiac insufficiency.

## **WARNINGS AND PRECAUTIONS**

Any sign or symptom of anaphylactic reaction (such as fever, shivering, rash or dyspnoea) should lead to immediate interruption of the infusion.

There is at present no clinical experience of the use of Structolipid in children and limited experience in patients with diabetes mellitus or renal failure.

Structolipid should be given with caution to patients with impaired lipid metabolism such as renal insufficiency, uncontrolled diabetes mellitus, pancreatitis, impaired liver function, hypothyroidism (if hypertriglyceridemic) and sepsis.

Triglyceride concentrations in serum should be monitored. When disturbed fat metabolism is suspected, this should be done daily. The serum triglyceride concentration should not exceed 3 mmol/L during the infusion. The next infusion should only be started when serum triglyceride levels have returned to the baseline.

Blood glucose levels, serum electrolytes, liver function tests, fluid balance, and blood status should be monitored regularly. When acidosis is suspected or occurs, acid-base balance should be monitored as well.

Structolipid should be administered simultaneously with carbohydrates to avoid the occurrence of metabolic acidosis.

Structolipid may interfere with certain laboratory measurements (e.g. bilirubin, lactate dehydrogenase, oxygen saturation, Hb) if blood is sampled before fat has been adequately cleared from the bloodstream. Fat is cleared after a fat-free interval of 5-6 hours in most patients.

Structolipid contains soya oil (in the form of purified structured triglycerides) and egg lecithin, which may rarely cause allergic reactions. Cross allergic reactions have been observed between soya-bean and peanut.

#### Pregnancy and lactation

No teratogenic or embryotoxic potential was evident in rabbits after infusions of Structolipid at a dosage of 3 g triglyceride (TG)/kg.day (0.75 g TG/kg/h) over 4 hours. At a dosage of 4.5 TG/kg/day (1.12 g TG/kg/h), a possible embryotoxic effect was evidenced by a slight increase in embryonic/foetal loss. The dosage and infusion rate were 3 and 7 times higher, than recommended for clinical use.

Drugs which have been taken by only a limited number of pregnant women and women of childbearing age, without an increase in the frequency of malformation or other direct or indirect harmful effects on the human fetus having been observed.

Studies in animals are inadequate or may be lacking, but available data show no evidence of an increased occurrence of fetal damage.

No clinical experience of use during breast-feeding is available. Women treated with Structolipid should not breast-feed.

#### Effects on ability to drive and use machines

Structolipid is presumed to be safe or unlikely to produce an effect on the ability to drive or use machinery

### **ADVERSE EFFECTS**

Common (incidence >1%)

During the clinical studies, nausea, headache and rises in body temperature have been recorded.

Increases in serum-triglycerides and ketone bodies have been reported during infusion of Structolipid. Liver function tests may show increased levels during parenteral nutrition regardless of whether fat is included or not.

Rare (incidence < 1%)

Structolipid has, when infused too fast, been shown to cause back pain of unknown origin.

Other adverse events that have occurred during treatment with Structolipid are respiratory symptoms, shivering, dizziness, diarrhoea, increased blood pressure, tachycardia, vomiting and macular rash.

### **Fat overload syndrome**

Impaired capacity to eliminate triglycerides can lead to “Fat overload syndrome”, which may be caused by overdose. This syndrome may also appear during severe hypertriglyceridaemia even at the recommended infusion rate, in association with a sudden change in the patient’s clinical condition, such as renal function impairment or infection. The fat overload syndrome is characterised by hyperlipaemia, fever, fat infiltration, hepatomegaly, splenomegaly, anaemia, leukopenia, thrombocytopenia, coagulation disturbances and coma. The symptoms are usually reversible if the infusion of the fat emulsion is discontinued.

### Interactions

Some medicines, like insulin, may interfere with the body’s lipase system. However, this kind of interaction seems to have little clinical significance.

Heparin given in clinical doses causes a transient release of lipoprotein lipase into the circulation. This may result initially in increased plasma lipolysis followed by a transient decrease in triglyceride clearance.

Soya oil has a natural content of vitamin K1. However, the concentration in Structolipid is so low that it is not expected to significantly influence the coagulation process in patients treated with coumarin derivatives.

### **OVERDOSAGE**

Refer to “Fat Overload syndrome” under “Adverse Effects”.

Severe overdose of fat emulsions containing MCT can, especially if carbohydrates are not administered simultaneously, lead to metabolic acidosis.

### **PHARMACEUTICAL PRECAUTIONS**

#### Instructions for Use/Handling

All-in-One mixing guidelines and limitations  
Additions should be made aseptically.

#### Compatibility with other drugs

##### Additives

Only medicinal, nutritional or electrolyte solutions for which compatibility has been documented may be added to Structolipid. (See All-in-One mixing guidelines and limitations under Dosage and Administration)

#### Mixing in plastic bag (phthalate-free film)

The plastic bag used for admixing has to be sterile and be made of phthalate-free film.

Mixtures made up with Structolipid should be prepared in a controlled and validated aseptic area.

Structolipid can be mixed with the amino acid solutions Glamin or Vamin 18 Electrolyte Free, glucose solutions, trace elements, vitamins, i.e. Soluvit and Vitalipid Adult, and electrolytes in the amounts indicated below.

Trace elements and electrolytes are added to the amino acid solution.

Inorganic phosphate supplements should be added to the glucose solution. The amino acid and glucose solutions with the additives are transferred to a plastic bag (phthalate-free film).

Vitamins, i.e. Soluvit and Vitalipid Adult can be added to Structolipid.

Finally, Structolipid with additives is transferred to the plastic bag which is turned with caution until a homogeneous mixture is obtained.

The content of vitamin C in the mixture decreases due to oxidation. Vitamin C deficiency in prolonged intravenous nutrition including Soluvit, has not been reported, however.

Limits for mixture components.

<i>Structolipid</i>	<i>250-750 ml</i>
<i>Glamin/Vamin 18 Electrolyte Free</i>	<i>500-1000 ml</i>
<i>Glucose 10% /</i>	<i>1000 ml</i>
<i>Glucose 20% /</i>	<i>1000-1500 ml</i>
<i>Glucose 30% /</i>	<i>500-1000 ml</i>
<i>Glucose 40% /</i>	<i>500 ml</i>
<i>Glucose 50%</i>	<i>500*-750**ml</i>
<i>Trace elements</i>	<i>0-10 ml</i>
<i>Vitalipid Adult</i>	<i>0-10 ml</i>
<i>Soluvit</i>	<i>0-1 bottle</i>

Electrolyte limits in ready-mixed bags

	mmol/1000 ml
Sodium	0-150
Potassium	0-150
Calcium	1-5
Magnesium	0.5-5
Phosphate ***	0-15

\* For stability reasons, 500 ml glucose 50% can only be mixed with 500-750 ml Structolipid when Glamin or Vamin 18 Electrolyte Free is used.

\*\* For stability reasons, 750 ml glucose 50% can only be mixed with

1. 1000 ml Glamin or Vamin 18 Electrolyte Free
2. 500-750 ml Structolipid.

\*\*\* Includes the amount from Structolipid.

## **Stability**

### Without additives

After opening the container, the emulsion should be used directly due to the risk of microbiological contamination. The left-over contents of an opened bag should be discarded and not saved for later use.

### Additives

When additions are made to Structolipid, the infusion should be used directly after preparation due to the risk of microbiological contamination. The left-over contents of an opened bag should be discarded and not saved for later use.

### Mixing in plastic bag (phthalate-free film)

The physical in-use stability has been demonstrated for 72 hours in a refrigerator (2-8°C) followed by an infusion period of up to 24 hours. From a microbiological point of view, the product should be used immediately after supplementation. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and should normally not be longer than 24 h at 2-8°C unless additions have taken place in controlled and validated aseptic conditions.

If the admixtures have been stored after mixing a cream layer can be presented. Turn gently until a homogenous mixture is obtained before use.

## **STORAGE**

Store below 25°C, do not freeze. Emulsions which have been frozen should be discarded. Any remaining emulsion from an opened bag must be discarded. Do not use if emulsion is discoloured. Stored correctly, Structolipid can be used until the expiry date printed on the labels.

Structolipid contains no preservatives.

### Gravity Dispersion

Separation of the product (gravity dispersion) occurs after a period of time and it should only be necessary to invert or shake the solution before usage. Do not use if inversion or gentle shaking does not result in an even mixture.

## **MEDICINES CLASSIFICATION**

General Sale Medicine

## **PACKAGE QUANTITIES**

Single packs of 250 mL or 500 mL bags

## **FURTHER INFORMATION**

Structolipid also contains glycerol, egg lecithin and water for injections.

## **NAME AND ADDRESS**

Fresenius Kabi New Zealand Limited  
60 Pavilion Drive

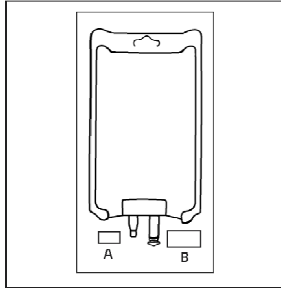
Airport Oaks, Auckland 2022  
New Zealand  
Freecall: 0800 144 892

**DATE OF PREPARATION**  
2<sup>nd</sup> December, 2010

## INSTRUCTIONS FOR USE

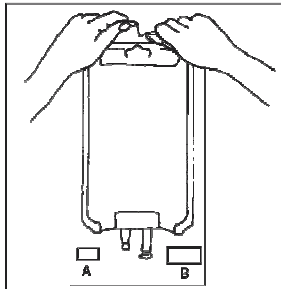
### Fresenius Kabi Infusion bag

1.



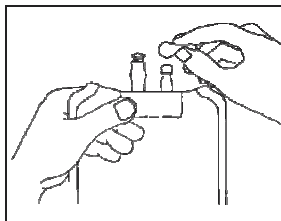
The integrity indicator (Oxalert™) A should be inspected before removing the overpouch. If the indicator is black the overpouch is damaged and the product should be discarded.

2.



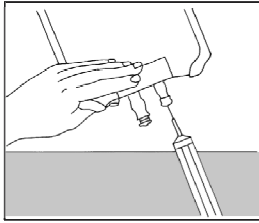
Remove the overwrap by tearing at the notch and pulling down along the container. The Oxalert™ sachet A and the oxygen absorber B should be disposed.

3.



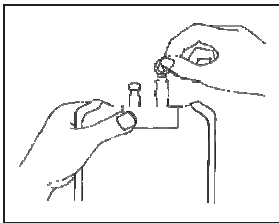
If additions are to be made, swab injection site.

4.



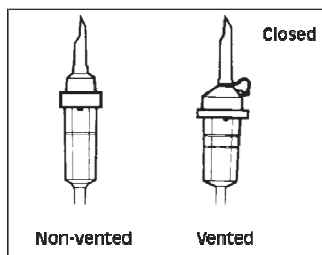
Place the container on a table and support the base of the medication port. Fully insert the needle through centre of injection site. Mix thoroughly by inverting container several times.

5.



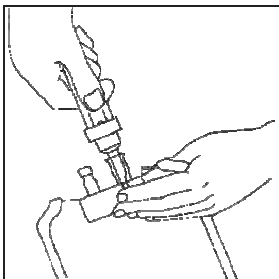
Remove set port cover lifting ring with thumb and forefinger and pulling upwards.

6.



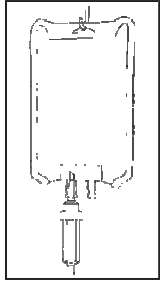
Use a non-vented infusion set or close the air vent on a vented set. Follow the instructions for use for the infusion set.

7.



The bag should be with the port side up when the infusion set is attached. Insert the spike straight into the set port. Twist and push the spike through the diaphragm. The spike should be fully inserted to ensure its retention.

8.



To hang the bag, invert and place hanger through container notch.