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 any further questions, ask your doctor, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:
1. What Structolipid is and what it is used for
2. What you need to know before you are given Structolipid
3. How you are given Structolipid
4. Possible side effects
5. How to store Structolipid
6. Contents of the pack and other information

1. What Structolipid is and what it is used for

Structolipid contains something called ‘triglycerides’ which is a type of ‘fatty acid’. The liquid contains a mixture of fats and water which is called a ‘lipid emulsion’.

- It works by providing energy and fats for your body
- It is put into your blood by a drip or an infusion pump.

Structolipid is given to adult patients as a complement when other forms of feeding are not good enough or have not worked.

2. What you need to know before you are given Structolipid

You should not be given Structolipid:

- if you are allergic to triglycerides or any of the other ingredients of this medicine (listed in section 6)
- if you are allergic to any other products containing egg, soy or peanut.
- if you have too much fat in the blood (called ‘severe hyperlipemia’).
- if you have serious liver disease.
- if you have a problem with your blood clotting system (called ‘hemophagocytic syndrome’).
- if you have severe blood clotting problems (called ‘coagulation disorders’).
- if you are in acute shock.
- if you have fluid in the lungs (called ‘pulmonary oedema’), too much body fluid (called ‘hyperhydation’) or have heart failure.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before you are given Structolipid if you have a problem with high levels of lipids in the blood due to that your body cannot use fat properly (called ‘impaired lipid metabolism’).

Structolipid may interfere with the results of certain laboratory tests.

Allergic reactions

If you have an allergic reaction while having Structolipid, it needs to be stopped straight away. Tell the doctor or nurse straight away if you get any of the following while you are having the infusion:

- fever (high temperature)
- shivering
- rash
- difficulty breathing

**Children**
Structolipid has not yet been used in children.

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

In particular, tell your doctor if you are taking or have recently taken drugs used to stop blood clotting, such as warfarin and heparin.

- Structolipid naturally contains vitamin K\(_1\), which can affect warfarin. However, the vitamin K\(_1\) content in Structolipid is so low that such problems are unlikely.
- Heparin given in clinical doses may at first cause higher levels of fatty acids in the blood due to liberation of fatty acids from the tissues into the bloodstream and then less fatty acids are removed from your blood (decreased triglyceride clearance).

**Pregnancy and breast-feeding**
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 you are given this medicine.

**Pregnancy**
It is not known whether it is safe to have Structolipid while you are pregnant. If you need to have direct feeding into your vein during pregnancy, your doctor will give you Structolipid only after careful consideration.

**Breast feeding**
If you are breast-feeding, do not have Structolipid.

**Driving and using machines**
No effects on the ability to drive and operate machines are to be expected.

3. **How you are given Structolipid**

Structolipid is put into your blood by a drip or an infusion pump. Your doctor will decide your dose depending on your body weight and your ability to get rid of the amount of fat infused.

For medical and health care professionals, please see “Method of administration” at the end of this leaflet for more details regarding dosage and administration.

**If you are given more Structolipid than you should**
In case the dose Structolipid given to you is too high, there is a risk of taking in too much fat. This is called ‘fat overload syndrome’. See section 4, Possible side effects, for more information.

**If you do not have carbohydrates (glucose) at the same time as Structolipid**
If you do not have carbohydrates given into your blood as well as Structolipid, this may result in a low pH in the blood (called ‘metabolic acidosis’). If this happens, your doctor will stop the treatment with Structolipid.

4. **Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**Fat overload syndrome**
This might happen when your body has problems using fat, because of having too much Structolipid. It may also happen because of a sudden change in your condition (such as kidney problems or infection). The fat overload syndrome is characterized by high levels of fat in the blood (hyperlipidemia), fever, fat infiltration and disorders in various organs of the body and coma. All symptoms will usually disappear when you stop having the infusion.
**Common** (may affect up to 1 in 10 people)
- headache
- feeling sick (nausea)
- rise in body temperature
- higher levels of fats known as triglycerides in the blood (called ‘hypertriglyceridaemia’)
- too much acid in the blood (called ‘ketosis’).

**Uncommon** (may affect up to 1 in 100 people)
- shivering
- diarrhoea
- being sick (vomiting)
- back pain.

**Very rare** (may affect up to 1 in 10,000 people)
- high blood pressure
- feeling dizzy
- fast heart rate
- more enzymes than usual that show how the liver is functioning
- difficulty in breathing
- rash.

**Reporting of side effects**
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

[To be completed nationally]

5. **How to store Structolipid**

Keep this medicine out of the sight and reach of children.

Do not store above 25°C.

Do not freeze.

Do not use Structolipid after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

Do not use Structolipid if you notice that the inner or outer bag is damaged (a small plastic bag filled with liquid will turn black if the outer bag is damaged). Use only if the solution is white and homogenous. For single use only. Any unused product should be thrown away. Do not re-use it.

Do not throw away medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. **Contents of the pack and other information**

**What Structolipid contains**

- The active substance is
  Purified structured triglyceride 200.0 mg/ml

- The other ingredients are
  Purified egg phospholipids
Glycerol
Sodium hydroxide
Water for injections

What Structolipid looks like and contents of the pack

Structolipid is a white, homogenous emulsion and is available in plastic bags, protected by an outer bag.

Pack sizes:
1 x 250 ml, 10 x 250 ml
1 x 500 ml, 12 x 500 ml

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
[To be completed nationally]

Manufacturer:
Fresenius Kabi AB, SE-751 74 Uppsala, Sweden

This leaflet was last revised in 2015-05-06

The following information is intended for healthcare professionals only:

Warnings and precautions for use

This medicinal product contains soybean oil (in the form of purified structured triglycerides), which may rarely cause allergic reactions. Cross-allergic reactions have been observed between soybean and peanut. Any sign or symptom of anaphylactic reaction (such as fever, shivering, rash or dyspnoea) should lead to immediate interruption of the infusion.

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

Method of administration

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

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.

Precautions for disposal and other handling

The integrity indicator (Oxalert) should be inspected before removing the overpouch. If the indicator is black, oxygen has penetrated the overpouch and the product should be discarded.

COMPATIBILITY

Additives
Only medicinal, nutritional or electrolyte solutions for which compatibility has been documented may be added to Structolipid. Compatibility for different additives and the storage time of the different admixtures will be available upon request. Additions should be made aseptically.
The normal daily requirement of water-soluble and fat-soluble vitamins, i.e. one bottle of SOLUVIT and one ampoule of VITALIPID ADULT, can be added to STRUCTOLIPID.

Before being added, SOLUVIT is reconstituted in either 10 ml of sterile water, STRUCTOLIPID or VITALIPID ADULT.

**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, VAMIN 18 ELECTROLYTE FREE or INTRAFUSIN 15%, glucose solutions, trace elements in the form of TRACEL, vitamins, i.e. SOLUVIT and VITALIPID ADULT, and electrolytes in the amounts indicated in the Summary of Product Characteristics.

TRACEL and electrolytes are added to the amino acid solution.

ADDIPHOS or any other inorganic phosphate source 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.

**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.