Package leaflet: Information for the user

Intralipid 10% w/v emulsion for infusion
Purified soya-bean oil

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

What is in this leaflet

1. What Intralipid 10% is and what it is used for

Intralipid 10% is used as a source of calories and fatty acids when you cannot eat normally. Intralipid 10% is particularly useful following trauma, infections or severe burns.

Intralipid 10% may be mixed with carbohydrates, amino acids, salts, vitamins and trace elements which together provide your complete nutritional needs.

2. What you need to know before you are given Intralipid 10%

Do not use Intralipid 10% if you:
• are allergic (hypersensitive) to Intralipid 10% or any of the ingredients of Intralipid 10% mentioned in section 6 (for symptoms of an allergic reaction, please refer to section 4)
• have a disorder of fat metabolism such as in severe liver damage or if you have suffered from shock

Warnings and precautions

Talk to your doctor or pharmacist before using Intralipid 10% if you suffer from:
• an allergy to products containing egg, soya or peanut oil.
Your doctor will carry out an allergy test to make sure you can receive this medicine.
• **reduced liver** function
• a condition where your body has **problems using fat** properly
• impaired **kidneys**
• any problems with your **pancreas**
• untreated **diabetes mellitus**
• **thyroid** problems- hypothyroidism
• **sepsis** (a condition in which your body is fighting a severe infection)
• metabolic disorders

When used in neonates and children below 2 years, the solution (in bags and administration sets) should be protected from light exposure until administration is completed. Exposure of Intralipid 10% to ambient light, especially after admixtures with trace elements and/or vitamins, generates peroxides and other degradation products that can be reduced by protection from light exposure

If Intralipid 10% is given to your newborn baby, tell your doctor if they have been born prematurely or were of a low birth weight or has high blood pressure in the lungs (pulmonary hypertension), so that they can be monitored closely.

This medicine may interfere with certain laboratory tests. It is important to tell any doctor doing tests that you are using Intralipid 10%.

Your doctor may want to do regular blood tests to make sure your body is using Intralipid 10% correctly.

Other medicines and Intralipid 10%
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Inform your doctor if you are taking
• any anticoagulants to help prevent blood clots, eg. heparin or warfarin
• insulin for the treatment of diabetes mellitus

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 or pharmacist for advice before taking this medicine. The doctor will decide if you should receive Intralipid 10%.

Driving and using machines

Intralipid 10% does not affect your ability to drive or use machinery.

3. How to use Intralipid 10%

You will receive your medicine by intravenous infusion (IV drip). The amount and rate at which the infusion is given depends on your requirements. Your doctor will decide on the correct dose for you or your baby to receive. You will be monitored during your treatment.

When used in neonates and children below 2 years, the solution (in bags and administration sets) should be protected from light exposure until administration is completed (see section 2).

If you receive too much Intralipid 10%
It is very unlikely that you will receive more infusion than you should as your doctor or nurse will monitor you during the treatment. However, if you think you received too much Intralipid 10% inform your doctor or nurse immediately. In case of overdose there is a risk of taking in too much fat. This is called 'fat overload syndrome' (see below).
Fat overload syndrome
This might happen when your body has problems using fat, because of having too much Intralipid 10%. It may also happen because of a sudden change in your condition (such as kidney problems or infection). Possible signs are fever, fat infiltration, elevated fat levels, problems in various organs and coma. All these symptoms will usually disappear when you stop having the infusion.

If you have any further questions on the use of this product, ask your doctor or nurse.

4. Possible side effects

Like all medicines, Intralipid 10% can cause side effects, although not everybody gets them.

Rise in body temperature, shivering, chills, feeling sick and being sick. **If this happens to you tell your doctor straight away, as Intralipid 10% administration needs to be stopped.**

Intralipid 10% may cause severe allergic reactions. If you get any of the following symptoms after receiving this medicine you should contact your doctor immediately:
• a rash appears on your body
• you have swollen face, tongue and throat
• you have difficulties breathing
• pale red itchy bumps causing a burning or stinging sensation

The following side effects have also been reported:

Extremely rarely (occurs in less than one in a million infusions)
• stomach pain
• headache
• blood and circulatory problems
• tiredness
• painful erections in men
• cholestasis- a condition in which bile is not flowing properly
from the liver to the intestines
• jaundice - skin and whites of eyes turn yellow
• abnormal liver test results- these will get back to normal after the treatment with Intralipid 10% is finished

Prolonged treatment with Intralipid 10% in infants has been reported to cause bleeding disorders.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.
You can also report side effects directly

In the UK: via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

In Ireland: HPRA Pharmacovigilance, Earlsfort Terrace, IRL- Dublin 2. Or by email to medsafety@hpre.ie

By reporting side effects you can help provide more information on the safety of this medicine

5. How to store Intralipid 10%

Keep this medicine out of the sight and reach of children.
Your doctor and hospital pharmacist are responsible for the correct storage, use and disposal of Intralipid 10% infusion. Do not store above 25°C. Do not freeze.
Do not use this medicine after the expiry date which is stated on the label. The expiry date refers to the last day of that month.
Do not throw away medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment**.**

When used in neonates and children below 2 years, the solution (in bags and administration sets) should be protected from light exposure until administration is completed (see section 2).

6. Contents of the pack and other information

What Intralipid 10% contains

One litre (1000 ml) contains the following: purified soybean oil 100 grams.
The other ingredients are purified egg phospholipids, glycerol, sodium hydroxide and water for injections

What Intralipid 10% looks like and contents of the pack

Intralipid 10% is a white fat emulsion (a mixture of oil and water). Intralipid 10% is supplied in sealed glass bottles which contains either 100 ml or 500 ml of this emulsion, biofine bags containing 100 ml or 500 ml of

emulsion. These bags are wrapped in an overpouch with an additional package in between the bag and the overpouch which is an oxygen absorber and integrity indicator.

Not all package sizes may be marketed.

Marketing Authorisation Holder

For UK:
Fresenius Kabi Limited
Cestrian Court, Eastgate Way
Manor Park
Runcorn, Cheshire
WA7 1NT, UK

For IRL:
Fresenius Kabi Deutschland GmbH
Else-Kröner-Straße 1, 61352 Bad Homburg, v.d.Höhe, Germany

Manufacturer:
Fresenius Kabi AB, SE-751 74 Uppsala, Sweden (plastic bags)

This leaflet was last revised in August 2019

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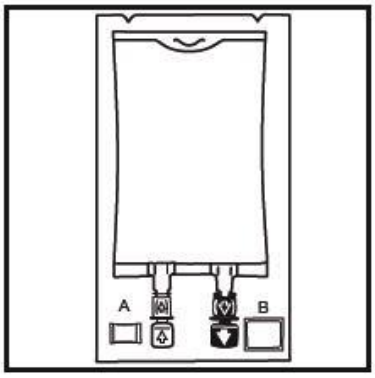
The following information is intended for healthcare professionals only.
Fresenius Kabi infusion bag

Method of administration:
When used in neonates and children below 2 years, the solution (in bags and administration sets) should be protected from light exposure until administration is completed

Special warnings and precautions for use:
Light exposure of solutions for intravenous parenteral nutrition, especially after admixture with trace elements and/or vitamins, may have adverse effects on clinical outcome in neonates, due to generation of peroxides and other degradation products. When used in neonates and children below 2 years, Intralipid 10%should be protected from ambient light until administration is completed.

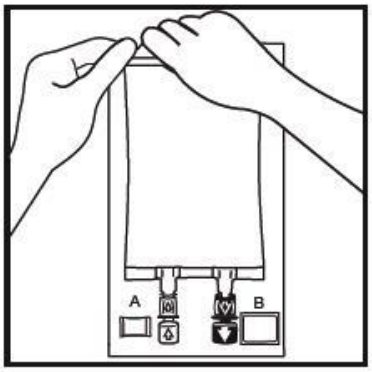
Instructions for use – Fresenius Kabi infusion bag

1.



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

2.



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.

3. If additives are to be used break off the tamper-evident arrow flag from the white additive port. If no additives (with known compatibility) are to be used go to figure 5.

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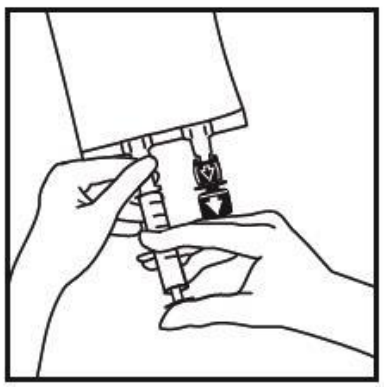
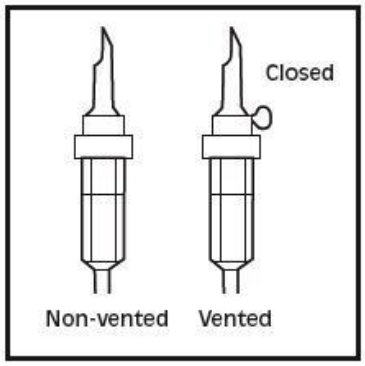
4.



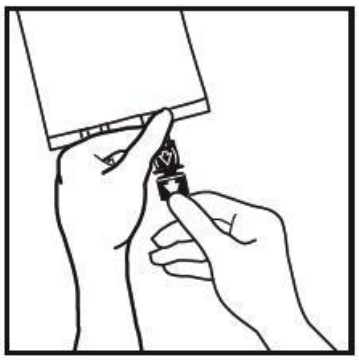
4. Insert the needle horizontally through the centre of the septum of the additive port and inject the additives (with known compatibility). Use syringes with needles of 18 - 23 gauge and a length of max. 40 mm.

5.



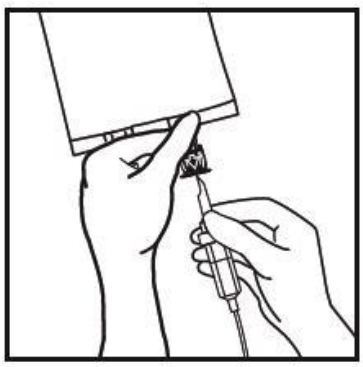
5. Use a non-vented infusion set or close the air vent on a vented set. Follow the instructions for use for the infusion set. Use a spike with diameter as specified in ISO 8536-4, 5.6 +/- 0.1 mm

6.



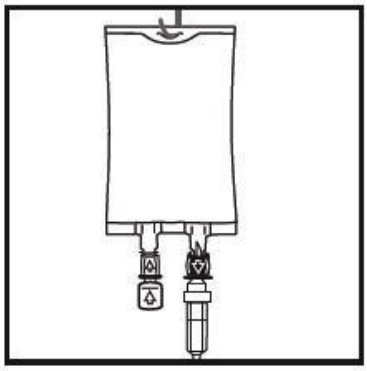
6. Break off the tamper-evident arrow flag from the blue infusion port.

7.



7. Hold the base of the infusion port. Insert the spike through the infusion port, by rotating your wrist slightly until the spike is inserted,

8.



8. Hang the bag in the hanger cut and start infusion.