PROFESSIONAL INFORMATION

SCHEDULING STATUS

S3

1 NAME OF THE MEDICINE

INTRALIPID® 20 %

Emulsion for intravenous infusion

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 000 mL contains:

Purified soybean oil	200 g
Energy content:	8 400 kJ (2 000 kcal) /1 000 mL

Contains sugar (as anhydrous glycerol 22,0 g/1 000 mL)

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Emulsion for intravenous infusion.

A white, homogenous emulsion.

Osmolality:	350 mosm/kg water
pH:	approx. 8

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

INTRALIPID 20 % is indicated as a source of energy and essential fatty acids for patients requiring intravenous nutrition. INTRALIPID 20 % is also specifically indicated for use in

infants and children.

INTRALIPID 20 % is also indicated for patients with essential fatty acid deficiency who cannot maintain or restore a normal essential fatty acid pattern by oral intake, for example:

Pre- and post-operative nutritional disturbances in which a large supply of energy is necessary or desirable, e.g. in order to improve the nitrogen balance.

Nutritional disorders or disturbances of nitrogen balance due to inadequate or failing intestinal absorption, caused by tumours in the gastrointestinal tract, or acute and chronic intestinal disease (peritonitis, ulcerative colitis and terminal ileitis).

Burns: In extensive burns, every additional supply of energy is of value as a means of reducing the frequently excessive nitrogen losses. A larger supply of energy also improves the utilisation of orally ingested protein.

Intravenously administered fat is also indicated in patients in whom oral nutrition is inadequate.

Cases where true feeding is inappropriate or impossible, e.g. during unconsciousness following cranial trauma or poisoning.

Impaired renal function, in which case an adequate supply of energy is essential to reduce protein breakdown.

Cachexia.

4.2 Posology and method of administration

Posology:

Adults:

The quantity of intravenously administered fat should not normally exceed 3 g/kg body weight per day.

INTRALIPID 20 % can supply up to 70 % of the energy requirements of the patient (also in patients with highly increased energy requirements).

The infusion rate of INTRALIPID 20 % should be about 20 drops/minute initially, being continually increased until it can be stabilised at the desired rate after 30 minutes.

The infusion rate of INTRALIPID 20 % should not exceed 500 mL in 5 hours.

Neonates and infants:

INTRALIPID 20 % should be used in new-borns and infants. The infant's ability to eliminate fat should govern the dosage of INTRALIPID 20 %. The recommended dosage range in neonates and infants is 2,5 - 20 mL INTRALIPID 20 % per kg body weight per day. The rate of infusion should not exceed 0,17 g of triglycerides/kg/hour (4 g/kg in 24 hours).

In premature and low birth weight neonates, INTRALIPID 20 % should preferably be infused continuously over 24 hours. The initial dosage of 0,5 - 1 g/kg/day may be increased by 0,5 – 1 g/kg/day up to 2 g/kg/day. Only with close monitoring of the serum triglyceride concentration, liver tests and oxygen saturation, may the dosage be increased to 4 g/kg/day. No attempt should be made to exceed these rates in order to compensate for missed doses.

IMPORTANT: Fat elimination:

Adults:

The ability to eliminate fat should be tested in adult patients given INTRALIPID 20 % for more than one week.

This is done by collecting a blood sample before the infusion is started after a fat clearance period of 4 - 6 hours. Blood cells are then separated from plasma by centrifugation (1 200 – 1 500 rpm).

If the plasma is opalescent, the planned infusion should be postponed. The sensitivity of this method is, however, such that hypertriglyceridaemia can pass undetected. Therefore, it is recommended that serum triglyceride concentrations are measured in patients who are likely to have an impaired fat tolerance. In conditions mentioned under section 4.4, fat elimination should be closely monitored.

Neonates and infants:

In neonates and infants, the ability to eliminate fat should be tested regularly.

Measurement of serum triglyceride levels is the only reliable method.

Method of Administration:

INTRALIPID 20 % may be infused into the same central or peripheral vein as carbohydrate/amino acid solutions by means of a Y-connector near the infusion site. INTRALIPID 20 % may also be given in a phthalate-free plastic bag as one part of an all-in-one admixture also containing carbohydrates, amino acids, electrolytes, vitamins and trace elements. The admixture must be approved for physical stability, and additives may only be added to INTRALIPID 20 % where compatibility is documented. Vitalipid Novum Adult or Vitalipid Novum Infant and/or Soluvit Novum are recommended additives.

Admixtures, which have been aseptically prepared, shall be used within 7 days after preparation.

The admixtures should be stored in a refrigerator (2 – 8 °C) and when infused, a maximum infusion period of 24 hours should be kept.

N.B. THE CONTENTS OF AN OPENED BOTTLE ARE FOR A SINGLE INFUSION ONLY.

ANY REMAINING EMULSION FROM AN OPENED BOTTLE MUST BE DISCARDED.

4.3 Contraindications

Hypersensitivity to egg -, soy- or peanut protein or to the active substance or any of the excipients listed in section 6.1 (also see section 4.4).

INTRALIPID 20 % is contraindicated in patients with acute shock and in those with disturbances in lipid metabolism.

4.4 Special warnings and precautions for use

The ability of the patient to eliminate administered fat (INTRALIPID 20 %) should govern the dosage and infusion rate of INTRALIPID 20 % - see section 4.2 “**Fat elimination**”.

INTRALIPID 20 % should not be administered to patients with severe liver disease, hyperlipidaemia or other conditions where the ability to absorb or metabolise fat may be impaired e.g. renal insufficiency, (uncontrolled) diabetes mellitus, pancreatitis, impaired liver function, hypothyroidism (with hypertriglyceridemia) and sepsis. However, if administration of INTRALIPID 20 % is considered in such patients, close monitoring of the serum triglyceride

concentration, on a daily basis, is obligatory.

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 20 % should be protected from ambient light until administration is completed (see section 6.3 and 6.6).

INTRALIPID 20 % should be given with caution to neonates and premature babies with hyperbilirubinaemia and in cases with suspected pulmonary hypertension. In neonates, particularly premature babies on long-term parenteral nutrition, platelet count, liver tests and serum triglyceride concentrations should be monitored.

INTRALIPID 20 % contains soybean oil and egg phospholipids, which may rarely cause allergic reactions. Cross allergic reactions have been observed between soybean and peanut (see section 4.3).

4.5 Interactions with other medicines and other forms of interaction

Some medicines, like insulin, may interfere with the body's lipase system. This kind of interaction seems, however, to be of only limited clinical importance. Heparin in clinical doses causes a transient increase in lipolysis in plasma, resulting in a transient decrease in triglyceride clearance due to depletion of lipoprotein lipase.

Soybean oil has a natural content of vitamin K1. This is considered important only for patients treated with coumarin derivatives, which interfere with vitamin K1. INTRALIPID 20 % may interfere with certain laboratory measurements (e.g. bilirubin, lactate dehydrogenase, oxygen saturation, haemoglobin, etc.) if blood is sampled before fat has been adequately cleared from the blood stream. Fat is normally cleared after a period of 4 - 6 hours in most patients.

4.6 Fertility, pregnancy and lactation

Pregnancy

Successful and safe administration of INTRALIPID 20 % during pregnancy has been reported. Animal reproduction studies have not been carried out with INTRALIPID 20 %.

Breastfeeding

The safety in lactating women has not been established.

Fertility

No data available.

4.7 Effects on ability to drive and use machines

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

4.8 Undesirable effects

Blood and lymphatic system disorders:

Very rare (<1/10 000)

Haemolysis, reticulocytosis. Thrombocytopenia has been reported in association with prolonged treatment with INTRALIPID 20 % in infants.

Cardiac disorders:

Very rare (<1/10 000)

Circulatory effects (hyper/hypotension).

Respiratory, thoracic and mediastinal disorders:

The following side effect has been reported and the frequency is unknown:

Respiratory symptoms (e.g. tachypnoea).

Gastrointestinal disorders:

Uncommon (>1/1 000, <1/100)

Abdominal pain, nausea, vomiting, abnormal pain.

Hepato-biliary disorders:

Very rare (<1/10 000)

Transient increases in liver enzymes after prolonged intravenous nutrition with or without INTRALIPID 20 % have been noted.

Impaired capacity to eliminate INTRALIPID 20 % may lead to fat overload syndrome as a result of overdosage but also at recommended rates of infusion in association with prolonged administration or with a sudden change in the clinical condition, such as renal function impairment or infection (see section 4.9). Pigmentation of tissues after prolonged therapy has also been reported.

Skin and subcutaneous tissue disorders:

Very rare (<1/10 000)

Rash, urticaria.

Musculoskeletal and connective tissue disorders:

Very rare (<1/10 000)

Abdominal pain.

Reproductive system and breast disorders:

Very rare (<1/10 000)

Priapism.

General disorders and administration site conditions:

Uncommon (>1/1 000, <1/100)

Infusion of INTRALIPID 20 % may cause a rise in body temperature, shivering, chills, headache and tiredness.

Immune system disorders:

Very rare (<1/10 000)

Hypersensitivity reactions (anaphylactic reaction, skin rash, urticaria).

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are asked to report any suspected adverse drug reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website.

Healthcare providers are asked to report any suspected adverse drug reactions to the Holder of the Certificate of Registration at the following email address: safety.fksa@fresenius-kabi.com and to the relevant medicines regulatory authority in the country where the product is marketed.

4.9 Overdose

Impaired capacity to eliminate INTRALIPID 20 % may lead to fat overload syndrome as a result of overdose (but also at recommended rates of infusion, in association with a sudden change in the clinical condition, such as renal function impairment or infection). Fat overload syndrome is characterised by hyperlipidaemia, fever, fat infiltration and disorders of various organs (e.g. bone marrow depression, anaemia, thrombocytopenia, spontaneous bleeding and hepatosplenomegaly) and coma. Symptoms are usually reversible, if the infusion of INTRALIPID 20 % is discontinued.

Immediate reactions to the intravenous administration of soybean oil emulsion may be treated by the intravenous administration of corticosteroids and antihistamines. Treatment with adrenaline 0,5 mL to 1,0 mL (0,5 mg to 1,0 mg) of a 1:1 000 solution by subcutaneous or intramuscular injection may be necessary.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

A 25 Special foods

ATC-code B05B A02

This lipid emulsion is a sterile, non-pyrogenic fat emulsion for intravenous infusion as a source of energy and essential fatty acids, which contain purified soybean oil emulsified with purified egg-yolk phospholipids. Approximately 60 % of the fatty acids in these emulsions are essential fatty acids.

The lipid globule size and biological properties of these emulsions are similar to those of natural chylomicrons. INTRALIPID 20 % has an energy content of about 8 400 kJ/L (2 000 kcal/L).

5.2 Pharmacokinetic properties

Not applicable

5.3 Preclinical safety data

Not applicable

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Purified egg phospholipids

Glycerol (anhydrous)

Sodium hydroxide (for pH-adjustment)

Water for injections

6.2 Incompatibilities

Additives may only be added to INTRALIPID 20 % if the compatibility has been documented.

6.3 Shelf life

Shelf life of the medicine as packaged for sale:

24 months

Shelf life after first opening of the container:

The emulsion should be used directly due to the risk of microbiological contamination. Any unused emulsion should be discarded.

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 4.4 and 6.6).

6.4 Special precautions for storage

Store at or below 25 °C. Do not freeze.

6.5 Nature and contents of container

Pack sizes:

100 mL (10 x 100 mL or 20 x 100 mL)

250 mL

500 mL (12 x 500 mL)

1 000 mL

Not all pack sizes may be marketed.

The infusion bag consists of an inner bag and an overpouch. An oxygen absorber and integrity indicator are placed between the inner bag and the overpouch. The inner bag is the primary container for INTRALIPID 20 %. The overpouch provides protection during storage by contributing with barrier properties towards water and oxygen to the INTRALIPID 20 % container system. The oxygen absorber will absorb and bind oxygen remaining between the inner bag and the overpouch.

The integrity indicator will react with free oxygen and change from clear to black in case of a damaged overpouch.

- The inner bag is made of a multilayer polymer film, Biofine.

  The Biofine inner bag film consists of poly(propylene/ethylene) copolymer and thermoplastic elastomers (SEBS and SIS). The infusion and additive ports are made of polypropylene and a thermoplastic elastomer (SEBS) equipped with synthetic polyisoprene stoppers.
- The oxygen barrier overpouch consists of polyolefin and polyethylene terephthalate or polyolefin, polyethylene terephthalate and poly(ethyl vinyl) alcohol (EVOH).
- The oxygen absorber consists of iron powder in a polymer sachet.
- The integrity indicator (Oxalert™) consists of an oxygen sensitive solution in a polymer sachet.
- All packaging components are latex- and PVC-free.

6.6 Special precautions for disposal and other handling

Do not use if the package is damaged.

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.

When used in neonates and children below 2 years, protect from light exposure until administration is completed. Exposure of INTRALIPID 20 % to ambient light, especially after admixture with trace elements and/or vitamins, generates peroxides and other degradation products that can be reduced by protection from light exposure (see section 4.4 and 6.3).

Additives:

Additives must be added aseptically. Vitalipid Novum Adult or Vitalipid Novum Infant and/or Soluvit Novum may be added to INTRALIPID 20 %. Otherwise, INTRALIPID 20 % may only be mixed with other medicines, nutrient or electrolyte solutions for which compatibility is

documented.

7 HOLDER OF CERTIFICATE OF REGISTRATION

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8 REGISTRATION NUMBER(S)

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20 May 2026