Intralipid® 20% Pharmacy Bulk Package is not intended for addition, sodium hydroxide has been added to adjust the pH of the mixture program. It is made up of 20% Soybean Oil, 1.2% Egg Phosphatides, and 0.1% Purified Egg Phosphatides. The major component fatty acids are linoleic acid (44–62%), oleic acid (28%), palmitic acid (10–12%), and stearic acid (1.4–5.5%).These fatty acids have the following chemical structure:

\[
\begin{align*}
R1 & = \text{saturated or unsaturated fatty acid} \\
R2 & = \text{saturated or unsaturated fatty acid} \\
R3 & = \text{choline, ethanolamine, serine, inositol or glycine}
\end{align*}
\]

The major component fatty acids are linoleic acid (44–62%) and oleic acid (28%). Phospholipids also contain palmitic acid (10–12%) and stearic acid (1.4–5.5%). Where \( R1 \) is saturated and unsaturated fatty acids, \( R2 \) is a saturated or unsaturated fatty acid, and \( R3 \) is primarily either the choline or ethanolamine. \( R1 \) and \( R2 \) contain saturated and unsaturated fatty acids that abound in neutral fats. R 3 is primarily either the choline or ethanolamine.

**Clinical Pharmacology**

Intralipid® is metabolized and utilized as a source of energy and is the preferred source of essential fatty acids for patients requiring parenteral nutrition. Essential fatty acids are normally provided to the body by polyunsaturated fatty acids, mainly linoleic and linolenic acids. Intralipid® provides calories and essential fatty acids for patients requiring parenteral nutrition.

**CONTAINING AGENTS**

Intralipid® is a sterile, non‑pyrogenic fat emulsion intended as a source of calories and essential fatty acids in parenteral nutrition admixtures. It is made up of three‑in‑one or total nutrient admixtures (TNA) containing Intralipid® and other parenteral fluids. The TNA is a sterile preparation consisting of a mixture of neutral triglycerides of predominantly unsaturated fatty acids with the following structure:

**WARNINGS**

Intralipid® 20% is a 20% I.V. Emulsion with an overall concentration of 20% soybean oil emulsified in buffered 0.9% sodium chloride. Intralipid® has been reported to contain residual amounts of 2 mg/kg polyvinyl chloride (PVC) components. Intralipid® contains no theophylline, KCl, lactated Ringer’s solution, or hydrocoptin. Intralipid® contains 0.9% sodium chloride and 20% soybean oil emulsified with phospholipids and water. Intralipid® is a liquid fat emulsion intended as a source of calories and essential fatty acids for patients requiring parenteral nutrition.

**OVERDOSAGE**

In the event of fat overload during therapy, stop the infusion containing Intralipid® (20%) or 10% Intralipid® admixtures until visual evidence of fat clearances or symptoms of fat overload are noted. If no untoward reactions occur, the rate can be changed to permit use of Intralipid® and 10% Intralipid® V.F. Emulsions, and such a dilution should not be used for more than 4 hours. The daily dose should not exceed 2.5 g/kg of body weight (12.5 mL of Intralipid® 20% per kg). Intralipid® 20% contains residual amounts of 2 mg/kg polyvinyl chloride (PVC) components. Intralipid® must be used for no more than 4 hours of continuous therapy. The bag should be stored below 25°C (77°F) after the bag has been unopened. Intralipid® is not irradiated or methylated. Intralipid® 20% contains polyvinyl chloride (PVC) components. Intralipid® 20% is not recommended for use with blood. Intralipid® 20% also contains residual amounts of 2 mg/kg polyvinyl chloride (PVC) components. Intralipid® contains no theophylline, KCl, lactated Ringer’s solution, or hydrocoptin. Intralipid® contains 0.9% sodium chloride and 20% soybean oil emulsified with phospholipids and water. Intralipid® is a liquid fat emulsion intended as a source of calories and essential fatty acids for patients requiring parenteral nutrition.

**ADVERSE REACTIONS**

The adverse reactions observed can be separated into two classes:

1. Transitory reactions that are frequently encountered are due to the intravenous infusion of Intralipid® and include:
   - Hypersensitivity reactions (rash, urticaria, pruritus, angioedema, bronchospasm, hypotension, tachycardia, fever, chills, rigors, and other systemic symptoms)
   - Gastrointestinal symptoms (nausea, vomiting, diarrhea, abdominal pain, flatulence)
   - Intravascular irritation

2. Those reactions that are considered to be serious and/or life-threatening are:
   - Severe allergic reactions (anaphylaxis, angioedema, bronchospasm, hypotension, tachycardia, fever, chills, rigors, and other systemic symptoms)
   - Severe gastrointestinal symptoms (nausea, vomiting, diarrhea, abdominal pain, flatulence)
   - Intravascular irritation

If symptoms occur, the infusion should be discontinued and appropriate medical care should be administered.
Failure to follow the Mixing Guidelines and Limitations below, including recommended storage temperature, storage time, order of mixing, etc., may result in an unstable admixture.

Intralipid® 20% (A 20% I.V. Fat Emulsion) may be mixed with Amino Acid and Dextrose Injections where compatibility has been demonstrated. Additives known to be incompatible should not be used. Please consult with pharmacist. If, in the informed judgment of the physician, it is deemed advisable to introduce additives, use aseptic technique. Mix thoroughly when additives have been introduced. Do not store solutions containing additives.

When preparing the following proper mixing sequence must be followed to minimize pH related problems by ensuring that typically acidic Dextrose Injections are not mixed with lipid emulsions alone:

1. Transfer Dextrose Injection to the TPN (Total Parenteral Nutrition) Admixture Container
2. Transfer Amino Acid Injection
3. Transfer Intralipid® 20%

Note: Amino Acid Injection, Dextrose Injection and Intralipid® 20% may be simultaneously transferred to the admixture container using an automatic mixer. Admixing should be accompanied by gentle agitation to avoid localized concentration effects.

Additives must not be added directly to Intralipid® 20%. In 20% I.V. Fat Emulsion Pharmacy Bulk Package and in no case should Intralipid® 20% be added to the TPN container first.

Bags should be shaken gently after each addition to minimize localized concentration.

If the admixture is not used immediately, the in-use storage time and conditions prior to use are the responsibility of the user and should normally not be longer than 24 hours at 2–8°C. After removal from storage at 2–8°C, the admixture should be infused within 24 hours.

It is essential that the admixture be prepared using strict aseptic techniques as this nutrient mixture is a good growth medium for microorganisms.

Supplemental electrolytes, trace metals or multivitamins may be required in accordance with the prescription of the attending physician.

The prime destabilizers of emulsions are excessive acidity (low pH) and inappropriate electrolyte content. Careful consideration should be given to addition of calcium (Ca++) and Mg++ which have been shown to cause emulsion instability. Calcium solutions exert a salting out effect promoting the emulsion. The admixture should be inspected carefully for "breaking or oiling out" of the emulsion. "Breaking or oiling out" is described as the separation of the emulsion and can be visually identified by the formation of yellow droplets in the admixed emulsion. The admixture must be discarded if any of the above is observed.

HOW SUPPLIED

Intralipid® 20% is supplied as a sterile emulsion in 1000 mL Pharmacy Bulk Package.

1000 mL: NDC 0338-0519-14

Intralipid® 20% is also available in the following fill sizes.

100 mL: 0338-0519-58
250 mL: 0338-0519-09
500 mL: 0338-0519-13

STORAGE

Intralipid® 20% should not be stored above 25°C (77°F). Do not freeze Intralipid® 20%. If accidentally frozen, discard the bag.

REFERENCES


Instruction for Use - Intralipid® 20% Pharmacy Bulk Package Container

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. 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. 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.

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

6. Hang the bag in the hanger cut and start transfer to the compounding bag.