

Intralipid®

(lipid injectable emulsion, USP 20%)

A long-standing and **chosen** **lipid** worldwide

- FDA approved for over 40 years
- 100% soybean oil
- Well documented in medical literature
- Provided in more than 200 million infusions* for adult and pediatric patients
- Established source of calories and essential fatty acids¹



Intralipid may be considered for patients requiring **parenteral nutrition (PN):**¹



- As a source of essential fatty acids for prevention of essential fatty acid deficiency (EFAD)
- When other lipid sources are not an option
- For inpatient use in both adults and children

INDICATION: Intralipid® is indicated as a source of calories and essential fatty acids for adult and pediatric patients requiring parenteral nutrition (PN) and as a source of essential fatty acids for prevention of essential fatty acid deficiency (EFAD). **CONTRAINDICATIONS:** Known hypersensitivity to egg, soybean, peanut, or any of the active or inactive ingredients in Intralipid. Severe disorders of lipid metabolism characterized by hypertriglyceridemia (serum triglyceride > 1,000 mg/dL).

Please see Indications and Important Safety Information on the reverse side.

Intralipid®

(lipid injectable emulsion, USP 20%)

INTRALIPID 20% COMPOSITION	
Content per 1L	Intralipid 20%
Soybean oil (g)	200
Osmolality (mOsm/kg water)	350
Inorganic phosphate (mmol)	15
Total caloric value (kcal/mL)	2

ORDERING INFORMATION					
Bag Size and Concentration	100 mL 20%	250 mL 20%	500 mL 20%	1000 mL 20%	500 mL 30%
NDC Code	65219-531-10	65219-535-25	65219-535-50	65219-539-10	65219-537-50
Bags/Case	10 bags/case	10 bags/case	12 bags/case	6 bags/case	12 bags/case

INDICATIONS AND USAGE

Intralipid 20% (A 20% Intravenous Fat Emulsion), is indicated as a source of calories and essential fatty acids for patients requiring parenteral nutrition (PN) and as a source of essential fatty acids for prevention of essential fatty acid deficiency (EFAD).

Intralipid 20% Pharmacy Bulk Package and Intralipid 30% Pharmacy Bulk Package are intended for use in a pharmacy admixture program for the preparation of three-in-one or total nutrition admixtures (TNAs) to provide a source of calories and essential fatty acids for adult and pediatric patients requiring PN and a source of essential fatty acids for prevention of EFAD.

INTRALIPID 20% and 30% PHARMACY BULK PACKAGES ARE NOT INTENDED FOR DIRECT INTRAVENOUS ADMINISTRATION.

IMPORTANT SAFETY INFORMATION

INTRALIPID 20% (A 20% INTRAVENOUS FAT EMULSION) PHARMACY BULK PACKAGE AND INTRALIPID 30% (A 30% INTRAVENOUS FAT EMULSION) PHARMACY BULK PACKAGE IS NOT INTENDED FOR DIRECT INTRAVENOUS ADMINISTRATION. DILUTING INTRALIPID 20% TO A 10% CONCENTRATION OR 30% TO A 10% OR 20% CONCENTRATION WITH AN INTRAVENOUS FLUID SUCH AS NORMAL SALINE OR OTHER DILUENT DOES NOT PRODUCE A DILUTION THAT IS EQUIVALENT IN COMPOSITION TO INTRALIPID 10% OR 20% I.V. FAT EMULSIONS, AND SUCH A DILUTION SHOULD NOT BE GIVEN BY DIRECT INTRAVENOUS ADMINISTRATION.

Recommended dosage depends on age, energy expenditure, clinical status, body weight, tolerance, ability to metabolize and eliminate lipids, and consideration of additional energy given to the patient. Protect the admixed PN solution from light. Use a 1.2 micron in-line filter during administration.

Dosage for Intralipid 20%

Age	Nutritional Requirements	
	Initial Recommended Dosage	Maximum Dosage
Birth to 2 years of age (including preterm and term neonates)	0.5 g/kg/day	3 g/kg/day
Pediatric patients 2 to <12 years of age	1 to 2 g/kg/day	2.5 g/kg/day
Pediatric patients 12 to 17 years of age	1 g/kg/day	2 g/kg/day
Adults	1 g/kg/day (stable) ≤1 g/kg/day (critically ill)	2.5 g/kg/day

Dosage for Intralipid 30%

Premature infants: initial dose at 0.5 g/kg/24 hours, maximum recommended dosage is 3g fat/kg/24hours.

Older pediatric patients: daily dose should not exceed 3 of g fat/kg/d.

Adults: The daily dosage should not exceed 2.5 g of fat/kg of body weight

Intralipid is contraindicated in patients with:

- Known hypersensitivity to egg, soybean, or peanut, or any of the active ingredients or excipients.
- Severe disorders of lipid metabolism characterized by hypertriglyceridemia (serum triglyceride > 1,000 mg/dL).
- Disturbances of normal fat metabolism such as pathologic hyperlipemia, lipid nephrosis or acute pancreatitis if accompanied by hyperlipidemia.

Risk of Clinical Decompensation with Rapid Infusion of Intravenous Lipid Emulsion in Neonates and Infants: Acute respiratory distress, metabolic acidosis, and death after rapid infusion of intravenous lipid emulsions have been reported.

Risk of Parenteral Nutrition-Associated Liver Disease (PNALD): Increased risk in patients who receive PN for extended periods of time, especially preterm neonates. Monitor liver function tests; if abnormalities occur consider discontinuation or dosage reduction.

Hypersensitivity Reactions: Monitor for signs or symptoms. Discontinue infusion if reactions occur.

Risk of Infections, Fat Overload Syndrome, Refeeding Syndrome, and Hypertriglyceridemia: Monitor for signs and symptoms; monitor laboratory parameters.

Aluminum Toxicity: Increased risk in patients with renal impairment, including preterm neonates.

Most common adverse drug reactions (≥5%) from clinical trials in adults were nausea, vomiting, and pyrexia. Most common adverse drug reactions (≥5%) from clinical trials in pediatric patients were anemia, vomiting, increased gamma-glutamyltransferase, and cholestasis.

Vitamin K Antagonists (e.g., warfarin): Anticoagulant activity may be counteracted; increase monitoring of coagulation parameters.

To report SUSPECTED ADVERSE REACTIONS, contact Fresenius Kabi USA, LLC at 1-800-551-7176, option 5, or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

This Important Safety Information does not include all the information needed to use Intralipid safely and effectively. Please see full prescribing information, for intravenous use at <https://freseniuskabinutrition.com/intralipid20PI> or <https://freseniuskabinutrition.com/intralipid30PI>

FOR MORE INFORMATION ABOUT INTRALIPID:

Website: www.FreseniusKabiNutrition.com
To Order: 1.888.386.1300
For coding/billing info: www.kabicare.us
Medical Information phone: 1.800.551.7176 (option 4)
Medical Information email: Nutrition.MedInfo.USA@fresenius-kabi.com

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*data on file

REFERENCE: 1. Intralipid Prescribing Information, Fresenius Kabi USA, LLC. 2023