

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 have 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 (e.g., Vitamins and Minerals).

When being mixed 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% (A 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 divalent cations (Ca⁺⁺ and Mg⁺⁺) which have been shown to cause emulsion instability. Amino acid solutions exert a buffering effect protecting 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 visibly identified by a yellowish streaking or the accumulation of yellowish droplets in the admixed emulsion. The admixture should also be examined for particulates. 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

1. Padley FB: "Major Vegetable Fats," The Lipid Handbook Gunstone FD, Harwood JL, Padley FB, eds.), Chapman and Hall Ltd., Cambridge, UK (1986), pp. 88-9.
2. Levene M, Wigglesworth JS, Desai R: Pulmonary fat accumulation after Intralipid® infusion in the preterm infant. Lancet 1980; 2(8199):815-8.
3. American Academy of Pediatrics: Use of intravenous fat emulsion in pediatric patients. Pediatrics 1981; 68:5(Nov) 738-43.

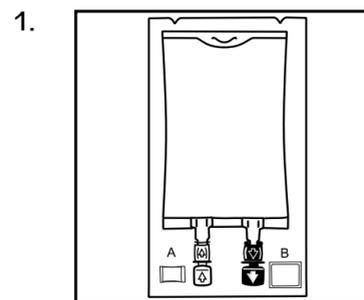
(Rev May 2015)

Manufactured for
Baxter Healthcare Corporation
Deerfield, IL 60015 USA

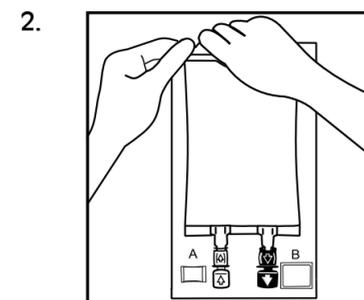
Manufactured by
Fresenius Kabi,
Uppsala, Sweden

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Fresenius Kabi AB.

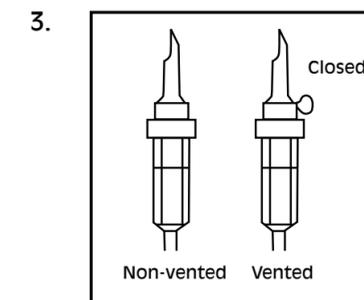
Instruction for Use - Intralipid® 20% Pharmacy Bulk Package Container



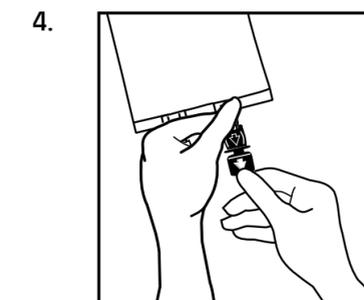
1. The integrity indicator (Oxalert™) **A** should be inspected before removing the overwrap. If the indicator is black the overwrap is damaged and the product should be discarded.



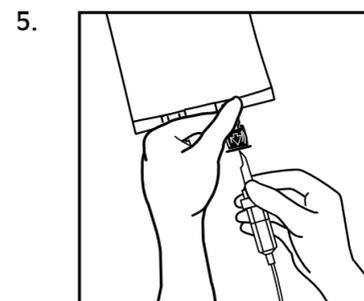
2. Remove the overwrap by tearing at the notch and pulling down along the container. The Oxalert™ sachet **A** and the oxygen absorber **B** should be disposed.



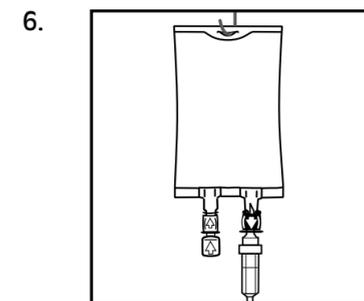
3. Use a non-vented infusion set or close the air vent on a vented set. Follow the instructions for use for the infusion set. Use a spike with diameter of 5.6 +/- 0.1 mm.



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



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.

