### 2.3 PREPARATION INSTRUCTIONS

Use the following instructions to prepare single-dose 100 mL, 200 mL, and 1000 mL Pharmacy Bulk Container in a separate area where:

1. Inspect Bag
   - Ensure the expected volume (100 mL, 200 mL, or 1000 mL) is present. Place bag on a non-slip mat. 
   - Ensure the bag and contents are unopened and unaltered. 
   - Visually inspect the bag and contents for particulate matter. Discard the Oxalert sachet (A) and the oxygen absorber (B). 

2. Rinse Infusion Set
   - Wash the set in warm water with soap. 
   - Rinse with clean water; do not use sterilization solution. 

3. Connect bag
   - Use a dedicated infusion line without any connections. Do not use any connections. 
   - Connect the bag to the intralipid admixture. 

4. Hang the bag
   - Hang the bag. 
   - Monitor the bag and contents. 

### Table 1: Recommanded Pediatric and Adult Dosage and Administration

<table>
<thead>
<tr>
<th>Type</th>
<th>Dosage Form</th>
<th>Strength</th>
<th>Rate</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single</td>
<td>100 mL Pharmacy Bulk Package</td>
<td>100 g/10 mL (10 g/mL)</td>
<td>0.2 mL/kg/hour</td>
<td>24 hours</td>
</tr>
<tr>
<td>Single</td>
<td>200 mL Pharmacy Bulk Package</td>
<td>200 g/20 mL (10 g/mL)</td>
<td>0.4 mL/kg/hour</td>
<td>24 hours</td>
</tr>
<tr>
<td>Single</td>
<td>1000 mL Pharmacy Bulk Package</td>
<td>1000 g/100 mL (10 g/mL)</td>
<td>0.2 mL/kg/hour</td>
<td>24 hours</td>
</tr>
</tbody>
</table>

### Warnings and Precautions

1. **1.1 Contraindications**
   - Known hypersensitivity to egg, soybean, peanut, or any of the active or inactive ingredients in Intralipid.
   - Hypersensitivity to Ca++ and Mg++ salts, which have been shown to cause emulsion decomposition.

2. **1.2 Precautions**
   - Infusion at a rate of 0.2 mL/kg/hour or greater may cause increased free fatty acid levels.
   - Avoid rapid administration.

3. **1.3 Adverse Reactions**
   - Hypersensitivity reactions, including anaphylaxis.
   - Anemia, vomiting, increased gamma-glutamyltransferase, and unexplained neurological changes.

4. **1.4 Laboratory and Other Tests**
   - Monitor hematocrit, albumin, bilirubin, and electrolyte levels.
   - Monitor triglyceride levels, particularly in neonates.

5. **1.5 Drug Interactions**
   - Drugs that may affect lipid and dextrose metabolism.

6. **1.6 Effects on Laboratory Findings**
   - Increased serum calcium, phosphorus, and magnesium levels.

7. **1.7 Impaired Renal Function**
   - Increased serum calcium, phosphorus, and magnesium levels.

### Full prescribing information

Intralipid 1000 mL Pharmacy Bulk Package

**INDICATIONS AND USAGE**

Intralipid is indicated for use in the parenteral nutrition (PN) and as a source of essential fatty acids for infants who require PN. Intralipid is not recommended for use in the prevention of essential fatty acid deficiency (EFAD).

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- Monitor triglyceride levels, particularly in neonates.

**DRUG INTERACTIONS**

- Drugs that may affect lipid and dextrose metabolism.

**EFFECTS ON LABORATORY FINDINGS**

- Increased serum calcium, phosphorus, and magnesium levels.

**IMPAIRED RENAL FUNCTION**

- Increased serum calcium, phosphorus, and magnesium levels.

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- Increased serum calcium, phosphorus, and magnesium levels.

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- Increased serum calcium, phosphorus, and magnesium levels.
Intralipid or equivalent soybean oil lipid emulsion and the comparator groups. The increase in mean triglyceride levels from baseline to the end of the study was 7.0 mmol/L (mean change) and 5.4 mmol/L (mean change) in the Intralipid and comparator groups, respectively.

PHARMACODYNAMIC EFFECTS

Clinical studies have not been performed in humans to evaluate the pharmacodynamic effects of Intralipid. Intralipid is designed to provide a source of long-chain triglycerides that are metabolized to free fatty acids and glycerol. These components are then transported in the blood to the liver, where fatty acids are reesterified into triglycerides and released into the blood for peripheral tissue uptake. The glycerol is metabolized primarily in the liver to gluconeogenesis.

PHARMACOKINETIC STUDIES

Intralipid is an intravenous lipid emulsion composed of a soybean oil triglyceride emulsion and is designed for use as a metabolic substrate to provide calories during parenteral nutrition. Intralipid is approved for use in adult and pediatric patients who require parenteral nutrition and is indicated for the provision of calories and fat-soluble vitamins. Intralipid is supplied as a flexible polyvinyl chloride bag containing 500 mL of lipid emulsion.

Adult Study 1 was a double-blind, randomized, active-controlled, parallel-group, multicenter study in patients who required PN during the period from 2009 to 2011. The study consisted of an initial single-blind, open-label phase followed by a randomized, controlled, double-blind phase. The study included adult patients who required PN for a minimum of 7 days and a maximum of 21 days. Intralipid was compared to a 4-oil mixed lipid emulsion in 333 patients (163 Intralipid; 170 comparator) who were treated with either Intralipid or the comparator for at least 7 days. The study lasted for a maximum of 21 days.

Table 3: Adverse Reactions in 60 to 84 Patients Treated with Intralipid or Placebo

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<td>4 (3%)</td>
</tr>
<tr>
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<td>5 (4%)</td>
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<td>8 (6%)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>8 (7%)</td>
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</tr>
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<td>Hypotension</td>
<td>7 (6%)</td>
<td>8 (7%)</td>
</tr>
<tr>
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