Public Summary

Summary for ARTG Entry:	48245 INTRALIPID 20% 500mL injection bottle
ARTG entry for	Medicine Registered
Sponsor	Fresenius Kabi Australia Pty Ltd
Postal Address	Level 2, 2 Woodland Way, Mount Kuring-gai, NSW, 2080 Australia
ARTG Start Date	8/03/1994
Product Category	Medicine
Status	Active
Approval Area	Drug Safety Evaluation Branch

Conditions

Conditions applicable to the relevant category and class of therapeutic goods as specified in the document "Conditions Applying to Therapeutic Goods Accepted for Registration or Listing as Goods Currently Supplied at the Commencement of the Therapeutic Goods Act 1989"

Conditions applicable to all therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995.

Conditions applicable to the relevant category and class of therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995.

Products

1 . Intralipid 20% 500mL injection bottle

Product Type	Single Medicine Product	**Effective Date**	5/09/2023 10:03:19 AM

Permitted Indications

No Permitted Indications included on Record

Indication Requirements

No Indication Requirements included on Record

Standard Indications

No Standard Indications included on Record

Specific Indications

INDICATIONS: Part of the intravenous diet in all parenteral nutrition indications including:- 1. preoperative and postoperative nutritional disturbances where an improved nitrogen balance is required; 2. nutritional disorders or disturbances of nitrogen balance due to inadequate or failing intestinal absorption caused by tumours in the gastrointestinal tract, acute or chronic intestinal diseases (peritonitis, ulcerative colitis, terminal ileitis); 3. burns, to reduce the frequently-excessive nitrogen losses; 4. prolonged unconsciousness, eg. following cranial trauma or poisoning in cases where enteral feeding is inappropriate or impossible; 5.impaired renal function where a concentrated source of energy may be indicated to reduce protein breakdown; 6. cachexia; 7. patients with essential fatty acid deficiency who cannot maintain or restore a normal essential fatty acid pattern by oral intake.

Warnings

See Product Information and Consumer Medicine Information for this product

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Bottle	Not recorded	2 Years	Store below 25 degrees Celsius	Not recorded	Do not Freeze

Pack Size/Poison information

Pack Size	Poison Schedule
500mL X 12	Not scheduled. Not considered by committee

Components

1 . Medicine Component

Dosage Form	Injection, intravenous infusion
Route of Administration	Intravenous
Visual Identification	Milky white liquid

Active Ingredients	
Soya Oil	**200 g/L**
Other Ingredients (Excipients)	
egg lecithin	
glycerol	
water for injections	

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