# Intralipid® 10%, 20% & 30%

# **Consumer Medicine Information (CMI) summary**

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

## 1. Why am I using Intralipid?

Intralipid contains the active ingredient soya oil. Intralipid is a supplement to parenteral nutrition, which provides your body with energy and fatty acids. It is usually given together with carbohydrates, amino acids, salts, trace elements and vitamins to provide a complete intravenous diet.

For more information, see Section 1. Why am I using Intralipid? in the full CMI.

### 2. What should I know before I use Intralipid?

• Do not use if you have ever had an allergic reaction to soy, eggs, peanuts or any of the ingredients listed at the end of the CMI. Tell your doctor if you have an inability to break down fats.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use Intralipid? in the full CMI.

# 3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with Intralipid and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

# 4. How do I use Intralipid?

The dose of Intralipid which you will require will be determined by your doctor or pharmacist. Your doctor will supervise
your treatment with Intralipid.

More instructions can be found in Section 4. How do I use Intralipid? in the full CMI.

## 5. What should I know while using Intralipid?

Things you should do	• Call you doctor straightaway if you have signs and symptoms of allergic reactions. In case of an allergic reaction, the infusion should be stopped immediately, and appropriate measures need to be taken.
Things you should not do	<ul> <li>Do not stop using this medicine without consulting your health care professional</li> <li>Do not take any other medicines without first telling your health care professional</li> <li>Do not give this medicine to anyone else, even if they have the same condition as you</li> </ul>
Driving or using machines	• The effects of this medicine on a person's ability to drive and use machines were not assessed as part of its registration.
Drinking alcohol	The effects of alcohol with Intralipid use were not studied. Your doctor will decide what you need to do.
Looking after your medicine	• Store below 25°C. Do not freeze it. Do not use Intralipid if it has been frozen. Do not use after the expiry date stated on the label.

For more information, see Section <u>5. What should I know while using Intralipid?</u> in the full CMI.

### 6. Are there any side effects?

Less serious side effects have been reported during post-marketing, including rise in body temperature, nausea, vomiting, shivering, chills, skin rash, hives, rapid breathing, shortness of breath, headache, effects on blood pressure, slight pressure over the eyes, abdominal pain, flushing and dizziness. If you get any adverse effects, talk to your doctor or nurse.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

Intralipid® 1

# Intralipid® 10%, 20% & 30%

Active ingredient: soya oil

# **Consumer Medicine Information (CMI)**

This leaflet provides important information about using Intralipid. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Intralipid.

#### Where to find information in this leaflet:

- 1. Why am I using Intralipid?
- 2. What should I know before I use Intralipid?
- 3. What if I am taking other medicines?
- 4. How do I use Intralipid?
- 5. What should I know while using Intralipid?
- 6. Are there any side effects?
- 7. Product details

### 1. Why am I using Intralipid?

**Intralipid contains the active ingredient soya oil.** Intralipid is a supplement to parenteral nutrition.

Soya oil consists of a mixture of mainly polyunsaturated fatty acids. Intralipid is a sterile fat emulsion, which provides your body with energy and fatty acids.

When the intake of nutrients or food into the mouth or directly into the gut is not possible or not enough to supply the needs, then intravenous nutrients or foods can be given. This is especially important for people under physical stress from illness or recent surgery.

Intralipid is usually given together with carbohydrates, amino acids, salts, trace elements and vitamins to provide a complete intravenous diet.

Intralipid is part of the intravenous diet in many situations where parenteral nutrition is required

# 2. What should I know before I use Intralipid?

#### Warnings

#### Do not use Intralipid if:

- you are allergic to soy, eggs, peanuts, or any of the ingredients listed at the end of this leaflet.
   Always check the ingredients to make sure you can use this medicine.
- if you have an inability to break down fats

#### Check with your doctor if you:

- are pregnant or trying to become pregnant
- are breastfeeding

- have any other medical conditions such as liver or kidney disease
- · are diabetic
- have a disease of the pancreas
- have a disorder of the thyroid gland
- are taking anticoagulants (medicines for preventing bold clotting)
- are taking any other medicines including any that you buy without a prescription from your pharmacy, supermarket or health food shop. These medicines may affect the action of Intralipid or may affect how well Intralipid works.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

#### Pregnancy and breastfeeding

It is not known whether Intralipid can cause harm to the baby when administered to pregnant women or can affect reproductive capacity.

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

#### Use in liver impairment

Intralipid is contraindicated in patients with an impaired ability to metabolise fat, such as severe liver damage. In cases of verified or suspected liver insufficiency the condition, as well as function, of the liver must be closely monitored.

#### Use in renal impairment

Intralipid should be used with caution in patients with impaired renal function as fat metabolism may be disturbed. The elimination of fat should be checked daily.

#### Use in elderly

No data is available for use of Intralipid in elderly patients. Your doctor will decide what to do.

#### **Use in Paediatrics**

Intralipid should be given with caution to neonates and premature infants with hyperbilirubinaemia and in cases with suspected pulmonary hypertension. In low birthweight infants, the risk of lipid infusions may outweigh potential benefits due to further diminution of defenses against infection.

Intralipid® 2

In infants, metabolism of lipids in peripheral tissues may be diminished by infection and heparin administration.

In neonates receiving long term parenteral nutrition, particularly premature neonates, platelet count, liver function tests and serum triglyceride concentration should be monitored.

When used in neonates and children below 2 years, Intralipid should be protected from ambient light until administration is completed.

# 3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

# Some medicines may interfere with Intralipid and affect how it works.

Tell your doctor or pharmacist if you are taking anticoagulants (medicines for preventing blood clotting) or any other medicines. Heparin in clinical doses causes a transient increase in lipolysis in plasma, resulting in a transient decrease in triglyceride clearance due to depletion of lipoprotein lipase.

Soya oil has a natural content of Vitamin  $K_1$ . This is considered important only for patients treated with coumarin derivatives, which interfere with Vitamin  $K_1$ . The dose of coumarin derivatives may need to be increased when soya oil containing fat emulsions are administered.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Intralipid.

#### 4. How do I use Intralipid?

#### How much is given

 The dose of Intralipid which you will require will be determined by your doctor or pharmacist.

#### How to take Intralipid

 Intralipid will be given to you by a health care professional. Your doctor will supervise your treatment with Intralipid.

#### If you forget to use Intralipid

This rarely happens as Intralipid is usually administered under the care of a trained health care professional in a hospital or clinic setting.

#### If you use too much Intralipid

This rarely happens as Intralipid is usually administered under the care of a trained professional in a hospital or clinic setting. However, if you are given Intralipid too quickly or too much, you may experience the following side effects: fever or convulsions.

If you think that you have used too much Intralipid, you may need urgent medical attention.

#### You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

# 5. What should I know while using Intralipid?

### Things you should do

#### Call your doctor straight away if you:

 have signs and symptoms of allergic reactions. In case of an allergic reaction, the infusion should be stopped immediately, and appropriate measures need to be taken.

Remind any doctor, dentist, pharmacist or nurse you visit that you are using Intralipid.

#### Things you should not do

 Do not stop using this medicine without consulting your health care professional.

#### **Driving or using machines**

Be careful before you drive or use any machines or tools until you know how Intralipid affects you.

The effects of this medicine on a person's ability to drive and use machines were not assessed as part of its registration.

#### **Drinking alcohol**

#### Tell your doctor if you drink alcohol.

The effects of alcohol with Intralipid use were not studied. Your doctor will decide what you need to do.

#### Looking after your medicine

Intralipid is usually administered under the care of a trained health care professional in a hospital or clinic setting.

Intralipid is recommended to be stored below 25°C in a cool dry place, protected from light, moisture or heat. Do not freeze. Do not use Intralipid if it has been frozen.

Keep it where young children cannot reach it.

Do not use this medicine after the expiry date which is stated on the carton label and the bottle or bag. The expiry date refers to the last day of that month.

Your doctor and hospital pharmacist are responsible for the correct storage, use and disposal of Intralipid.

# 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention. See the information below and, if you need to, ask your doctor or nurse if you have any further questions about side effects.

The below less serious side effects were reported during post-market monitoring.

#### Less serious side effects

Less serious side effects	What to do
<ul> <li>rise in body temperature</li> <li>nausea, vomiting</li> <li>shivering &amp; chills</li> <li>skin rash &amp; hives</li> <li>rapid breathing &amp; shortness of breath</li> <li>headache</li> <li>effects on blood pressure</li> <li>slight pressure over the eyes</li> <li>abdominal pain</li> <li>flushing</li> <li>dizziness</li> </ul>	Speak to your doctor if you have any of these less serious side effects and they worry you.
Serious side effects	What to do
Hypersensitivity     reactions which may     include sudden signs     of allergy such as rash,     itching or hives on the     skin or swelling of the     face, lips, tongue or     other parts of the     body	Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

# Tell your doctor or nurse if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

#### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at <a href="https://www.tga.gov.au/reporting-problems">www.tga.gov.au/reporting-problems</a>. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

# 7. Product details

This medicine is only available with a doctor's prescription.

#### What Intralipid contains

Active ingredient (main ingredient)	soya oil 100 g/L (10%), 200 g/L (20%) & 300 g/L (30%)
Other ingredients	egg lecithin

(inactive ingredients)	glycerol sodium hydroxide (pH adjustment) water for injections
Potential allergens	Soy, egg, peanut

# Do not take this medicine if you are allergic to any of these ingredients.

Intralipid does not contain gluten, lactose, sucrose, tartrazine or any other azo dyes.

1000mL of Intralipid supplies the following calories:

10% 4600 kJ20% 8400 kJ30% 12600kJ

Intralipid comes in different pack sizes and can be identified by AUST numbers:

#### **Bottles**

Intralipid 10%, 500 mL	AUST R 14471
Intralipid 20%, 100 mL	AUST R 14472
Intralipid 20%, 500 mL	AUST R 48245
Intralipid 20%, 1000 mL	AUST R 48246
Intralipid 30%, 250 mL	AUST R 53538
Intralipid 30%, 333 mL	AUST R 53539
Intralipid 30%, 500 mL	AUST R 53540
Intralipid 30%, 1000 mL	AUST R 53541
Bags	
Intralipid 10%, 500 mL	AUST R 77744
Intralipid 20%, 100 mL	AUST R 77745
Intralipid 20%, 500 mL	AUST R 77746
Intralipid 30%, 250 mL	AUST R 77747
Intralipid 30%, 333 mL	AUST R 77748

#### What Intralipid looks like

Intralipid is a milky white emulsion which is supplied in glass bottles or plastic bags.

It may be supplied from the pharmacy as a mixture of amino acids, glucose, and vitamins. In this case it would be a milky white mixture in a plastic bag.

### Who distributes Intralipid

Fresenius Kabi Australia Pty Limited Level 2, 2 Woodland Way Mount Kuring-gai NSW 2080 Australia

Telephone: 1300 361 004

This leaflet was prepared in March 2023.

Intralipid® 4