

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 SMOFlipid?

SMOFlipid contains the active ingredients soya oil, medium chain triglycerides, olive oil and fish oil-rich in omega-3 fatty acids. SMOFlipid is a supplement to parenteral nutrition, which provides your body with nutrition by the intravenous route. It is usually given together with carbohydrates, amino acids and salts to provide an intravenous diet.

For more information, see Section [1. Why am I using SMOFlipid?](#) in the full CMI.

2. What should I know before I use SMOFlipid?

Do not use if you have ever had an allergic reaction to fish, 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 SMOFlipid?](#) in the full CMI.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking anticoagulants (medicines for preventing blood clotting) or 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 SMOFlipid 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 SMOFlipid?

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

More instructions can be found in Section [4. How do I use SMOFlipid?](#) in the full CMI.

5. What should I know while using SMOFlipid?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist, pharmacist or nurse you visit that you are using SMOFlipid.• 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 style="list-style-type: none">• Do not stop using this medicine without consulting your health care professional• Do not take any other medicines without first telling your health care professional• Do not give this medicine to anyone else, even if they have the same condition as you
Driving or using machines	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• The effects of alcohol with SMOFlipid use were not studied. Your doctor will decide what you need to do.
Looking after your medicine	<ul style="list-style-type: none">• Store below 25°C. Do not freeze. Do not use after the expiry date stated on the label.

For more information, see Section [5. What should I know while using SMOFlipid?](#) in the full CMI.

6. Are there any side effects?

Less serious side effects such as nausea, vomiting, headaches, and flatulence may occur. 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.

SMOFlipid®

Active ingredient: *soya oil, medium chain triglycerides, olive oil and fish oil-rich in omega-3 fatty acids*

Consumer Medicine Information (CMI)

This leaflet provides important information about using SMOFlipid. **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 SMOFlipid.**

Where to find information in this leaflet:

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

1. Why am I using SMOFlipid?

SMOFlipid contains the active ingredients **soya oil, medium chain triglycerides, olive oil and fish oil-rich in omega-3 fatty acids**. SMOFlipid is used for supply of energy and essential fatty acids via intravenous route. 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 food can be given. This is especially important for people under physical stress from illness or recent surgery.

2. WHAT SHOULD I KNOW BEFORE I USE SMOFLIPID?

Warnings

Do not use SMOFlipid if:

- you are allergic to fish, 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 one of the following conditions:
 - an abnormal level of lipids in the blood
 - severe liver failure
 - severe kidney failure (when dialysis facilities are not available)
 - severe blood coagulation disorders
 - not able to receive infusion therapy
- unstable, e.g. acute shock, uncompensated diabetes mellitus, heart attack, stroke, metabolic acidosis.

Check with your doctor if you:

- are at risk for having an abnormal level of lipid in the blood (severe sepsis, extremely low birth weight infant)
- have any other medical conditions such as liver, kidney, pancreas or thyroid disorders or diabetes
- 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 SMOFlipid or may affect how well SMOFlipid 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 SMOFlipid will harm your unborn baby or affect your 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 Paediatrics

SMOFlipid should be given with caution to neonates and premature infants with hyperbilirubinaemia and pulmonary hypertension.

When used in neonates and children below 2 years, SMOFlipid 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 SMOFlipid and affect how it works.

Tell your doctor or pharmacist if you are taking anticoagulants (medicines for preventing blood clotting) such as heparin or any other medicines. **Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect SMOFlipid.**

4. How do I use SMOFlipid?

How much is given

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

How to use SMOFlipid

- SMOFlipid will be given to as a continuous infusion into a vein. A cannula (administration needle) is placed in a vein by your health care professional. This is normally done in a health institution but in some cases at home. An electronic pump may be used to control the speed of the infusion of drip.
- The infusion is for or single use in one person only.

If you forget to use SMOFlipid

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

If you use too much SMOFlipid

This rarely happens as SMOFlipid is usually administered under the care of a trained professional in a hospital or clinic setting. However, if you are given SMOFlipid too quickly or too much, you may experience the following side effects: feeling sick (nausea and vomiting) or becoming flushed and sweaty. These effects usually reversed if the infusion is discontinued.

Your doctor has information on how to recognise and treat an overdose. Ask your doctor if you have any concerns.

If you think that you have used too much SMOFlipid, 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 SMOFlipid?

Things you should do

- Remind any doctor, dentist, pharmacist or nurse you visit that you are using SMOFlipid.
- 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.
- Discuss with your health care professional your progress, especially if any complications occur during therapy. Frequent clinical evaluations and laboratory tests maybe required.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how SMOFlipid 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 SMOFlipid use were not studied. Your doctor will decide what you need to do.

Looking after your medicine

SMOFlipid is usually administered under the care of a health care professional in a hospital or clinic setting. Your doctor and hospital pharmacist are responsible for the correct storage, use and disposal of SMOFlipid. It is recommended that SMOFlipid be stored below 25°C in a cool dry place, protected from light and away from moisture or heat. The product should not be frozen.

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.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">• Nausea and vomiting• headaches• increased blood triglyceride or sugar level	Speak to your doctor if you have any of these less serious side effects and they worry you.

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.

Telephone: 1300 361 004

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 www.tga.gov.au/reporting-problems. 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.

This leaflet was prepared in March 2023.

7. Product details

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

What SMOFlipid contains

Active ingredients (main ingredients)	soya oil 60 g/L medium chain triglycerides 60 g/L olive oil 50 g/L fish oil-rich in omega-3 fatty acids 30 g/L
Other ingredients (inactive ingredients)	egg lecithin dl-alpha-tocopherol (Vitamin E) glycerol sodium hydroxide (pH adjustment) sodium oleate water for injections
Potential allergens	Fish, soy, peanut, egg

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

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

Total energy: 8400 kJ (2000kcal) / 1000mL.

Osmolality: 380 mOsm/kg water

pH: approx. 8

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

10 or 20 x 100mL bags (Aust R 262963)

10 x 250mL bags (Aust R 262964)

12 x 500mL bags (Aust R 158359)

What SMOFlipid looks like

SMOFlipid is a milky white emulsion which is supplied in plastic bags packaged in a protective over wrap.

Who distributes SMOFlipid

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