

SMOFlipid® 20%

Emulsion for intravenous infusion

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about SMOFlipid. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you given SMOFlipid against any benefits they expect it will have for you.

If you have any questions about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What is SMOFlipid used for

SMOFlipid is a sterile emulsion which provides your body with nutrition by the intravenous route. When the intake of nutrients or food into the mouth or directly into the gut is not possible, or it is not enough to supply the body's needs, then intravenous nutrients or foods can be given. This is especially important for people whose bodies are under physical stress from illness or recent surgery. During illness or after surgery the body requires nutrition or food.

SMOFlipid contains Soya oil, Medium chain triglycerides, Olive oil and Fish oil. SMOFlipid is usually given together with carbohydrates,

amino acids and salts to provide an intravenous diet.

Before you are given SMOFlipid

When you must not take it

- If you have had an allergic reaction like fever, shivering, rash or breathing difficulties to fish, egg-yolk containing foods, peanut or soy products.
- If you are allergic to any of the ingredients in this medicine.
- If you have an inability to break down fats
- If you have severe liver failure.
- If you have severe kidney failure (when dialysis facilities are not available).
- If you are suffering from a very serious problem with your blood circulation.
- If you have too much fluid in your body.
- If you have too much acid in your blood, also called metabolic acidosis.
- If you have a build up of fluid in your lungs and
- If you have certain untreated heart problems.
- If you are suffering from a blood disease or an infection of the blood.
- If you are experiencing a sudden decrease in blood pressure.
- If you have too much sugar in your blood.

- If there is not enough water content in your body.
- If you are suffering from a severe unstable medical condition as a result of or after injury.
- If you are experiencing a sudden blocking of an artery by a blood clot (stroke).

If you are not sure whether any of these apply to you, check with your doctor.

Before you start to take it

Tell your doctor BEFORE being given SMOFlipid if the answer to any of the following questions is YES.

- Are you pregnant or trying to become pregnant?
- Are you breastfeeding?
- Are you allergic to proteins of eggs, peanuts, soy or fish or any other medicines or any other substances, such as foods, preservatives or dyes?
- Do you have liver or kidney disease?
- Are you a diabetic?
- Do you have a disease of the pancreas?
- Do you have a disorder of the thyroid gland?
- Do you have a blood infection?
- Do you have high lipid levels in your blood?

Taking other medicines

Tell your doctor or pharmacist if you are taking anticoagulants (medicines for preventing blood clotting) or any other medicines.

How to take SMOFlipid

How much to take

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 take it

This medicine will be administered to you by a healthcare professional as a continuous infusion into a vein. An electronic pump may be used to control the speed of the infusion of drip.

If you are given too much (overdose)

This rarely happens as SMOFlipid is 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 become flushed and sweaty.

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

Otherwise, immediately telephone your doctor or contact the Poisons Information Centre in your country.

Australia: 13 11 26
New Zealand: 0800 764 766.

Side Effects

SMOFlipid, like all other nutrient solutions which are given intravenously, may cause unwanted effects in some people. All the unwanted effects associated with SMOFlipid may not yet have been detected.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- nausea and vomiting
- headaches
- flatulence

If you have these or any other unwanted effects during treatment, tell your doctor or nurse.

Storage

The expiry date of SMOFlipid is on the label of the pack. SMOFlipid should not be used if the expiry date has passed.

SMOFlipid should be stored below 25°C, but not frozen. Do not use SMOFlipid if it has been frozen.

Disposal

The contents of each bag of SMOFlipid are for single infusion only. Any unused SMOFlipid should be discarded. Do not use SMOFlipid if it is discoloured.

Product Description

Total energy supplied by SMOFlipid is 2000kcal / 1000mL

Osmolality: 380 mOsm/kg water
pH: Approximately 8.

What it looks like

SMOFlipid is a milky white emulsion which is supplied in plastic bags.

SMOFlipid comes in different bag sizes:
10 or 20 x 100mL (AUST R 262963)
10 x 250mL (AUST R 262964)
12 x 500mL (AUST R 158359)

Ingredients

SMOFlipid contains Soya oil, Medium Chain Triglycerides, Olive oil and Fish oil - rich in Omega-3 acids.

SMOFlipid also contains other ingredients such as glycerol, egg lecithin, dl-alpha-tocopherol (Vitamin E), sodium hydroxide, sodium oleate and water for injections.

SMOFlipid does not contain any preservative.

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

Further Information

More detailed information is available from your doctor or pharmacist. Therefore, if you have any concerns about the information or about SMOFlipid please ask your doctor or pharmacist.

Sponsor

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This leaflet was prepared in September 2021.