PATIENT INFORMATION LEAFLET

Scheduling status: S3

SMOFlipid 20 % Emulsion for intravenous infusion

Refined soybean oil, medium-chain triglycerides, refined olive oil, fish oil

Sugar free

Read all of this leaflet carefully before you are given SMOFlipid

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.

What is in this leaflet

1. What SMOFlipid is and what it is used for

SMOFlipid is used to supply energy, essential fatty acid and omega-3 fatty acids to patients when oral or enteral (food via a tube through the nose) nutrition is impossible, insufficient or contraindicated.

2. What you need to know before you are given SMOFlipid

You should not receive SMOFlipid:

- If you are hypersensitive (allergic) to fish, egg, soya or peanut protein or to any of the other ingredients of SMOFlipid listed in section 6.
- If you have high lipid (fat) levels.
- If you have liver or kidney problems.
- If you have blood clotting disorders.
- If you are in acute shock.
- If you have fluid in the lungs (called 'pulmonary oedema'), too much body fluid (called 'hyperhydration') or have heart failure (due to too much body fluid).
- If you have an unstable condition , for example after serious injury, blood clot (thrombosis), metabolic acidosis (metabolic disturbance which results in high acid levels in the blood), blood poisoning, untreated diabetes mellitus, stroke or heart attack.

If you think you may be allergic, tell your doctor without receiving SMOFlipid.

Warnings and precautions

Special care should be taken with SMOFlipid:

- If you have high lipid (fat) levels (reduction of the dosage or discontinuation of the treatment should be considered).
- If you have allergies to soya, fish, peanut and egg products.
- If you have impaired lipid metabolism, which may occur in patients with kidney failure, diabetes, infection of the pancreas, impaired liver function, hypothyroidism and severe infection.
- Blood lipid and glucose levels should be monitored.
- An overdose of the treatment may lead to a condition called "Fat overload syndrome".

Allergic reactions

If you have an allergic reaction while having SMOFlipid, it needs to be stopped immediately. Tell the doctor or nurse immediately if you get any of the following while you are having the infusion:

- fever (high temperature)
- shivering
- rash
- difficulty in breathing.

If any of these apply to you, tell your doctor before receiving SMOFlipid.

Children

Caution should be taken in neonates and premature neonates.

When used in neonates and children below 2 years, the solution (in bags and administration sets) should be protected from light exposure until administration is completed. Exposure of SMOFlipid to ambient light, especially after admixtures with trace elements and/or vitamins, generates peroxides and other degradation products that can be reduced by protection from light exposure.

Talk to your doctor or nurse if this medicine is being given to your newborn child and they have:

- too much of a substance called “bilirubin” in their blood (hyperbilirubinaemia)
- a high pressure in their lungs (pulmonary hypertension).

If your newborn child has SMOFlipid for a long time the doctor will take blood tests to see how it is working.

Other medicines and SMOFlipid

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

SMOFlipid may interfere with some other medicines.

This includes heparin, an injection used to treat blood clotting. Heparin should be administered with caution during your treatment with SMOFlipid. If you are using heparin, your doctor might prescribe other alternative medicines.

You should also tell your doctor if you are already receiving SMOFlipid and you are prescribed a new medicine you have not taken previously during SMOFlipid treatment.

SMOFlipid with food and drink

Not applicable. Your doctor or nurse will administer the product to you in a hospital setting via an injection.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before receiving SMOFlipid.

There is no information available on the use of SMOFlipid in pregnant or breastfeeding women. SMOFlipid should only be given after careful consideration.

Driving and using machinery

Your doctor or nurse will administer the product to you in a hospital setting via an injection.

SMOFlipid contains sodium

SMOFlipid contains up to 5 mmol (115 mg) sodium per 1000 ml. To be taken into consideration by patients on a controlled sodium diet.

3. How you will be given SMOFlipid

You will not be expected to give yourself SMOFlipid. It will be given to you by a person who is qualified to do so.

Your doctor or nurse will administer the product to you in a hospital setting via an injection, at a dose that is suitable for you. The frequency of administration and the duration of treatment will also be determined by the doctor.

Monitoring your SMOFlipid treatment:

You will have regular tests to monitor blood lipid and glucose levels during treatment to see how SMOFlipid is tolerated. If you have any questions about how SMOFlipid works or why it has been prescribed for you, ask your doctor.

Older people (age 65 years and over):

SMOFlipid can be given to people aged 65 years and over at the same dose as for other adults.

Children and adolescents (below the age of 18 years):

SMOFlipid can be given to neonates, infants and children at a dose that will be determined by the doctor.

If you are given more SMOFlipid than you should

Since a healthcare provider will administer SMOFlipid, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

In case the SMOFlipid dose given to you is too high, there is a risk of taking in more fat than your body can handle. This is called 'fat overload syndrome'. See section 4.

4. Possible side effects

SMOFlipid can have side effects.

Not all side effects reported for SMOFlipid are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while receiving SMOFlipid, please consult your doctor, pharmacist or other healthcare provider for advice.

If any of the following happens, stop using SMOFlipid and tell your doctor immediately:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to SMOFlipid.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Slight increase in body temperature.

Less frequent side effects:

- Lack of appetite, nausea and vomiting
- Chills.

The following other side effects have been reported in patients treated with SMOFlipid:

- Low blood pressure
- High blood pressure
- Difficulty in breathing
- Painful erections in men
- Allergic reactions (e.g. high temperature, swelling, lowering of blood pressure, skin rash, redness, headache)
- Heat or cold sensations
- Paleness
- Bluish discolouration of skin and mucous membranes (due to reduced oxygen content in the blood)
- Pain in the neck, back, bones, chest and loins.

Fat overload syndrome:

This might happen when your body has problems using fat, because of having too much SMOFlipid. It may also happen because of a sudden change in your condition (such as kidney problems or infection). The fat overload syndrome is characterised by high levels of fat in the blood (hyperlipidemia), fever, more fat in your tissues than normal (fat infiltration) and disorders in various organs of the body and coma. All symptoms will usually disappear when you stop having the infusion.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of SMOFlipid.

5. How to store SMOFlipid

Store all medicines out of reach of children.

Store at or below 25 °C. Do not freeze.

Your doctor or nurse will be responsible for the safe storage and proper disposal of SMOFlipid.

Do not use SMOFlipid after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

Do not use SMOFlipid if you notice that the package is damaged. Use only if the emulsion is homogenous. Any unused product should be discarded.

When used in neonates and children below 2 years, the solution (in bags and administration sets) should be protected from light exposure until administration is completed.

6. Contents of the pack and other information

What SMOFlipid contains

- The active substances in 1 000 ml emulsion are:

Refined soybean oil	60,0 g
Medium-chain triglycerides	60,0 g
Refined olive oil	50,0 g
Fish oil, rich in omega-3 fatty acids	30,0 g

- The other ingredients are:

Egg lecithin, glycerol, sodium oleate, sodium hydroxide (for pH-adjustment), antioxidant vitamin E (DL-α-tocopherol) and water for injections.

What SMOFlipid looks like and contents of the pack

SMOFlipid is a white homogeneous emulsion for intravenous infusion.

SMOFlipid is packaged in glass bottles. The clear glass bottles are packed with a professional information leaflet into outer cardboard cartons as follows:

10 x 100 ml, 10 x 250 ml, 10 x 500 ml.

Not all pack sizes may be marketed.

Holder of the certificate of registration

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Access to the corresponding Professional Information

The professional information will be printed and packed with the product.