

PART III: CONSUMER INFORMATION

SMOFlipid[®] 20%

Lipid Injectable Emulsion, Mfr. Std.

Soybean oil, medium chain triglycerides, olive oil and fish oil (6%/ 6%/ 5%/ 3% w/v)

Lipid Emulsion for Intravenous Nutrition

This leaflet is part III of a three-part "Product Monograph" published when SMOFlipid 20% was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about SMOFlipid 20%. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

SMOFlipid 20% is used in adults to provide energy, essential fatty acids and omega-3 fatty acids from fish oil. It is administered into your blood by a drip or an infusion pump.

A healthcare professional will recommend you SMOFlipid when you are unable to take food by mouth or other forms of feeding have not worked (e.g. nasogastric tube, direct catheter).

What SMOFlipid 20% does:

SMOFlipid 20% helps to ensure adequate intake of calories and essential fatty acids and thus helping to prevent or treat malnutrition.

When SMOFlipid 20% should not be used:

It is contraindicated to administer SMOFlipid if:

- you are allergic (hypersensitive) to fish, eggs or any of the ingredients of SMOFlipid. (See **What the important nonmedicinal ingredients are**)
- you are allergic to peanuts or soya. SMOFlipid contains soybean oil.
- you have especially high levels of fats in your blood (severe hyperlipidemia).
- you have severe reduced liver function (severe liver insufficiency).
- you have severe blood clotting disorders.
- you have severe impaired kidney function (severe renal insufficiency) without access to hemofiltration or dialysis.
- you are in an acute shock.
- you have the following general contraindications to infusion therapy: critical fluid accumulation in your lungs (acute pulmonary edema), excess water content of your body (hyperhydration), and decompensated heart failure (decompensated cardiac insufficiency).

- you are suffering from a heart attack, acute stroke, metabolic acidosis (too much acid in the blood), severe infection (sepsis), dehydration or a blockage in the arteries.
- you have an unstable medical conditions.

What the medicinal ingredient is:

Each 100 mL contains:

Soybean oil, refined	6.0 g
Triglycerides, medium-chain	6.0 g
Olive oil, refined	5.0 g
Fish oil, rich in omega-3 acids	3.0 g

What the important nonmedicinal ingredients are:

Purified egg phospholipids	1.2 g
All- <i>rac</i> - α -tocopherol	16-23 mg
Glycerol	2.5 g
Sodium oleate	30 mg
Sodium hydroxide	to adjust pH

What dosage forms it comes in:

SMOFlipid 20% is a white homogeneous lipid emulsion. You will receive your medicine by infusion.

WARNINGS AND PRECAUTIONS

BEFORE you use SMOFlipid 20% talk to your doctor or pharmacist if:

You have any diseases/conditions listed in contraindications section (see **When it should not be used**)

Care should be taken when administrating SMOFlipid 20%, therefore inform you doctor if:

- you are pregnant or planning to become pregnant.
- you are breast feeding or planning to breastfeed.
- you are taking any other medications.
- you have high level of lipids in your blood.
- you have allergy to soybean, fish or eggs, which may rarely cause allergic reactions. Peanut may also cause reactions to patients, who are allergic to soybean.
- any sign or symptom of allergic reaction (such as fever, shivering, rash or breathlessness) occurs during the treatment.
- you have impaired metabolism, which may occur if you have kidney or liver problems, diabetes, pancreatitis (inflammation of the pancreas), thyroid problems (hypothyroidism), and sepsis (infection).

INTERACTIONS WITH THIS MEDICATION

Drugs that may interact with SMOFlipid 20%

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Soybean oil has a natural content of vitamin K₁. The amount in SMOFlipid however is minimal and not expected to significantly counteract the blood-thinning (anticoagulant) activity of coumarin derivatives.

There may also be interaction between SMOFlipid 20% and heparin.

Inform your doctor if you are taking any anticoagulants to help prevent blood clots, e. g. heparin or coumarin derivatives.

Drug-Laboratory Interactions

This medicine may interfere with certain laboratory tests. It is important to tell any doctor doing tests that you are using SMOFlipid 20%.

PROPER USE OF THIS MEDICATION

SMOFlipid 20% may be mixed by health care professionals with carbohydrates, amino acids, salts, vitamins and trace elements which together provide your complete nutritional needs.

SMOFlipid can be given in a hospital or managed care facility, or at home under the supervision of a doctor or other health care professional.

After appropriate training and with the agreement of your health care team, you may be able to administer yourself a compounded TPN admixture containing SMOFlipid prepared by pharmacy professionals under aseptic conditions.

Use only if the compounded emulsion is homogeneous and milk-like. Use only if the bag is not damaged. Aseptic conditions must be followed. The bag should only be used once. Discard unused portion. Do not use a partially used bag.

Usual adult dose:

You will receive your medicine by intravenous infusion. The amount and rate at which the infusion is given depends on your individual requirements and your medical condition (please also see section “WARNINGS AND PRECAUTIONS”).

Your doctor will decide on the correct dose for you.

Your doctor will also specify a flow rate corresponding to your needs and medical condition.

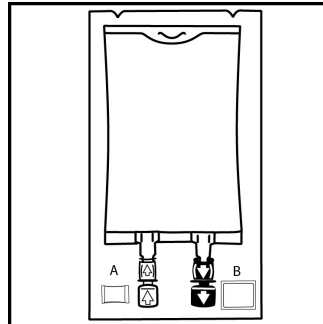
Instructions for use and handling

Before administering the product in plastic bags to patient, review these directions:

IV emulsion

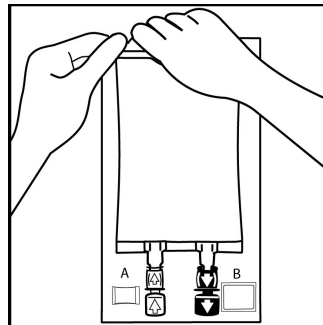
These instructions are only intended as guidelines for product use. Please refer to your own departmental guidelines.

1.



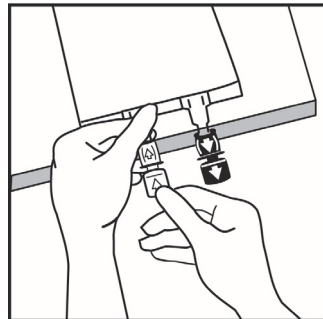
The integrity indicator (Oxalert™) A should be inspected before removing the overwrap. If the indicator is black the overwrap is damaged and the product should be discarded.

2.



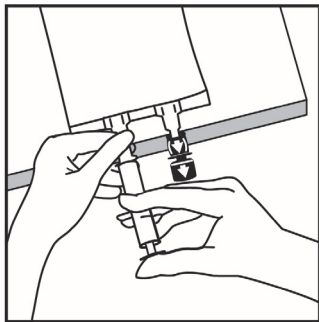
Place the bag on the clean, flat surface. Remove the overwrap by tearing at the notch and pulling down along the container. The Oxalert™ sachet A and the oxygen absorber B should be discarded.

3.



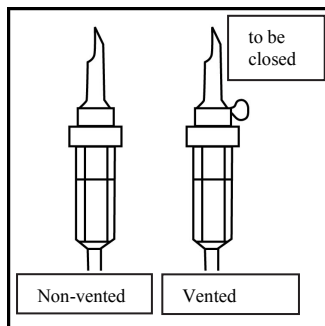
Place the bag on the clean, flat surface. If additives are to be used break off the tamper-evident arrow flag from the white additive port. If no additives are to be used go to figure 5.

4.



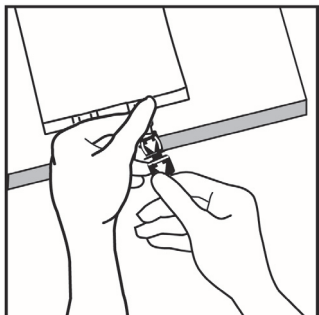
Place the bag on the clean, flat surface. Insert the needle horizontally through the centre of the septum of the additive port and inject the additives (with known compatibility). Use syringes with needles of 18-23 gauge and a length of max. 40 mm.

5.



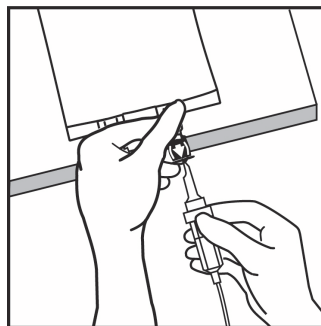
Use a non-vented infusion set or close the air vent on a vented set. Follow the instructions for use for the infusion set. Use a spike with diameter as specified in ISO 8536-4, 5.6 +/- 0.1 mm.

6.



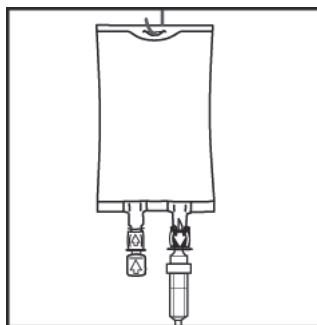
Place the bag on the clean, flat surface. Break off the tamper-evident arrow flag from the blue infusion port.

7.



Place the bag on the clean, flat surface. Hold the base of the infusion port. Insert the spike through the infusion port, by rotating your wrist slightly until the spike is inserted.

8.



Hang the bag in the hanger cut and start infusion.

The medicine must be at room temperature to be administered.

Your doctor may monitor your condition and periodically test your blood and urine.

Overdose:

If you think that you have received too high dose or SMOFlipid 20% was infused too quickly, inform your doctor or nurse immediately. In case of overdose there is a risk of receiving too much fat. This is called “fat overload syndrome”. In these cases the fat infusion should be stopped or, if necessary, continued at a reduced dosage. See section “SIDE EFFECTS” for more information.

If you have any further questions on the use of this product, ask your doctor or nurse.

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, SMOFlipid 20% can cause side effects, although not everybody gets them.

If any symptoms of an allergic reaction develop, for example such as breathing difficulties, skin rash, urticaria, flush, headache, stop the infusion immediately and contact your doctor. Occasional redness and stinging may occur at the injection site.

Serious side effects observed during administration of lipid emulsions are listed in the table:

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom / effect		Talk with your doctor or nurse		Stop taking drug and call your doctor or nurse
		Only if severe	In all cases	
Uncommon	- Nausea, Vomiting, - Chills	√		NA
Rare	- low blood pressure, (hypotension), - high blood pressure (hypertension) - allergic reaction (e.g. breathing difficulties, skin rash, urticaria, flush, headache)		√ √	√

This is not a complete list of side effects. For any unexpected effects while taking SMOFlipid, contact your doctor or pharmacist

Fat overload syndrome

Possible symptoms of fat overload are fever, yellowing of the skin and eyes, abdominal pain, vomiting, anemia, fall in the number of white blood cells and platelets, troubles in blood clotting, liver and spleen enlargement and coma. Stop the medication if these symptoms occur. These symptoms usually disappear when the medication is stopped.

If you suffer such side effects, tell your doctor.

HOW TO STORE IT

Store up to 25 °C. Do not freeze.

REPORTING SIDE EFFECTS

You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

3 ways to report:

- online at MedEffect (www.healthcanada.gc.ca/medeffect)
- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form and sending it by:
 - Fax to 1-866-678-6789 (toll-free), or
 - Mail to: **Canada Vigilance Program
Health Canada
Postal Locator 0701E
Ottawa, ON
K1A 0K9**

Postage paid labels and the Consumer Side Effect Reporting Form are available at MedEffect.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

If you want more information about SMOFlipid®

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<http://hc-sc.gc.ca/index-eng.php>); the manufacturer's website (<http://www.fresenius-kabi.ca>), or by calling 1-877-821-7724 (toll-free-telephone).

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