

PART III: CONSUMER INFORMATION**SmofKabiven® Electrolyte Free**

Amino acids, dextrose and lipid injectable emulsion
5.1 % / 12.7 % / 3.8 %; w/v

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

ABOUT THIS MEDICATION**What the medication is used for:**

- Your healthcare professional will prescribe SmofKabiven Electrolyte Free to provide nutrition by infusion into a vein when normal feeding by mouth is not possible or appropriate for you.

What it does:

SmofKabiven Electrolyte Free contain a mixture of lipids (fats), carbohydrate, and amino acids to provide energy and nutrients when other forms of feeding are not enough or not possible. SmofKabiven Electrolyte Free may be further mixed by healthcare professionals with additional and compatible salts, vitamins and trace elements which together provide your nutritional support.

When it should not be used:

It is contraindicated to administer SmofKabiven Electrolyte Free if:

- you are allergic (hypersensitive) to fish, eggs, peanuts, soya or any of the ingredients of SmofKabiven Electrolyte Free (see what the nonmedicinal ingredients are).
- you have especially high levels of lipids in your blood (severe hyperlipidemia).
- you have severe reduced liver function (severe liver insufficiency).
- you have impaired congenital errors of amino acid metabolism.
- you have severe blood clotting disorder (e.g. severely reduced ability to stop bleeding).
- you have severely reduced kidney function (severe renal insufficiency) without access to dialysis or hemofiltration.
- you are in shock (e.g. life-threatening drop in blood pressure).
- you have uncontrolled levels of blood sugar.
- you have hemophagocytotic syndrome, a type of blood disorder.
- you have general contraindications to infusion therapy, or have critical fluid accumulation in your lungs (acute pulmonary edema), excess water content in your body (hyperhydration), and acute heart failure.
- you have an unstable medical condition.

What the medicinal ingredient are:

Amino acids, dextrose and lipid injectable emulsion (5.1 % /

12.7% / 3.8%), w/v in three chamber bags.

Each 100 mL of mixed product for SmofKabiven Electrolyte Free contains**Amino acids**

Alanine 710 mg, arginine 610 mg, glycine 560 mg, histidine 150 mg, isoleucine 250 mg, leucine 380 mg, lysine acetate 340 mg, methionine 220 mg, phenylalanine 260 mg, proline 570 mg, serine 330 mg, taurine 50 mg, threonine 220 mg, tryptophan 100 mg, tyrosine 20 mg and valine 310 mg

Lipid (fats)

Soybean oil 1140 mg, medium chain triglycerides 1140 mg, olive oil 950 mg and fish oil 570 mg

Dextrose

As glucose monohydrate 12.7 g

What the important nonmedicinal ingredients are:**Glycerol**

Purified egg phospholipids
all-rac- α -Tocopherol
Sodium hydroxide (pH adjuster)
Sodium oleate
Acetic acid, glacial (pH adjuster)
Hydrochloric acid (pH adjuster)
Water for injection

What dosage forms it comes in:

SmofKabiven Electrolyte Free consisting of three separate chambers: one chamber with a milk-like, homogenous lipid emulsion, one chamber containing a clear and colourless to slightly yellow amino acid solution and one containing a clear and colourless to slightly yellow dextrose solution. Before use, the seals between the chambers are broken, to mix the components together. Once mixed, SmofKabiven Electrolyte Free is an opaque, white, homogenous lipid emulsion. You will receive your SmofKabiven Electrolyte Free by intravenous infusion.

WARNINGS AND PRECAUTIONS**BEFORE you use SmofKabiven Electrolyte Free talk to your doctor or pharmacist if:**

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

Care should be taken when administering SmofKabiven Electrolyte Free, therefore inform your doctor if:

- you have high level of lipids in your blood.
- you have an allergy to soybean, fish or eggs, which may rarely cause allergic reactions; soybean may also cause reactions in patients who are allergic to peanut.
- you have impaired lipid and amino acid metabolism, which may occur if you have kidney or liver problems (renal failure, impaired liver function), diabetes mellitus, pancreatitis (inflammation of the pancreas), thyroid problems (hypothyroidism), or sepsis (e.g. life-threatening systemic infection).
- you have heart problems.
- you are pregnant or planning to become pregnant.

- you are breast feeding or planning to breastfeed.
- you are taking any other medications.

Contact your doctor immediately during treatment if the following occurs:

- any sign or symptom of allergic reaction (such as fever, shivering, rash, sweating and headache or breathlessness).

INTERACTIONS WITH THIS MEDICATION

Drugs that may interact with SmofKabiven Electrolyte Free:

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 SmofKabiven Electrolyte Free however, is minimal and not expected to significantly counteract the blood-thinning (anticoagulant) activity of coumarin derivatives.

There may also be an interaction between heparin and SmofKabiven Electrolyte Free.

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

Drug-Laboratory Interactions

This medicine may interfere with certain laboratory tests. It is important to tell any doctor doing tests that you are using SmofKabiven Electrolyte Free.

PROPER USE OF THIS MEDICATION

SmofKabiven Electrolyte Free 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 a parenteral nutrition admixture containing SmofKabiven Electrolyte Free by yourself. Additional nutrients may be added by pharmacy professionals. Use only if the mixed 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 any unused portion.

Usual adult dose:

You will receive your medicine by intravenous infusion into a central vein.

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 SmofKabiven Electrolyte Free should be infused continuously for 14 to 24 hours.

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

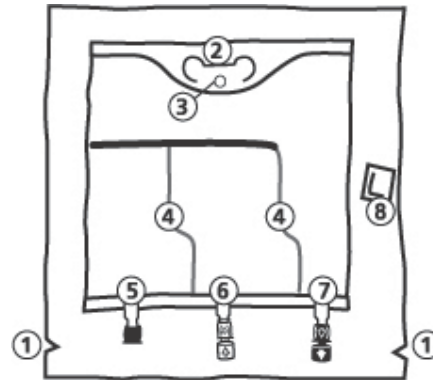
SPECIAL HANDLING INSTRUCTIONS

Instructions for use and handling

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

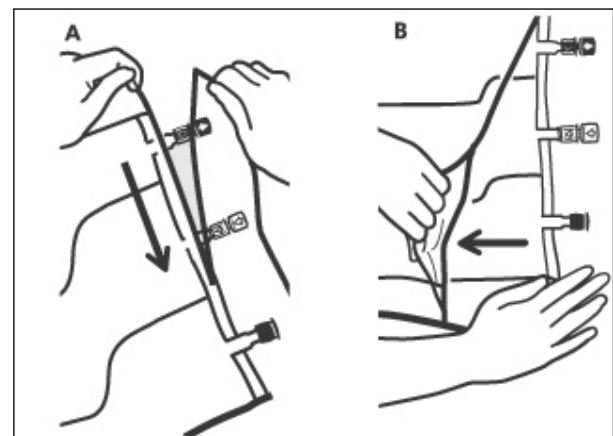
These instructions are only intended as guidelines for product use. Please ask your healthcare provider for detailed instructions on handling?

The bag



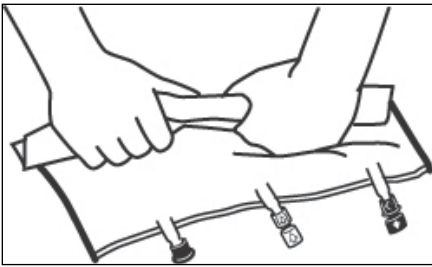
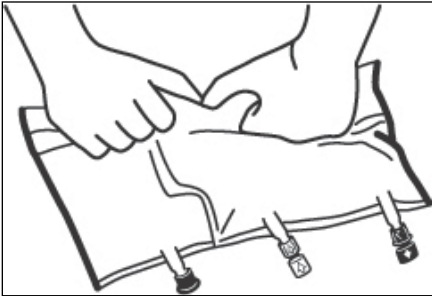
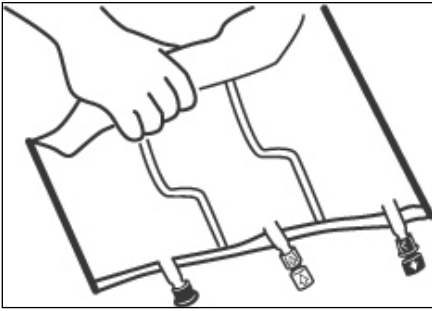
1. Notches in the overwrap
2. Handle
3. Hole for hanging the bag
4. Vertical seals
5. Blind port (only used during manufacturing)
6. WHITE Additive port
7. BLUE Infusion port
8. Oxygen absorber (present between bag and inside overwrap).

1. Removal of overwrap



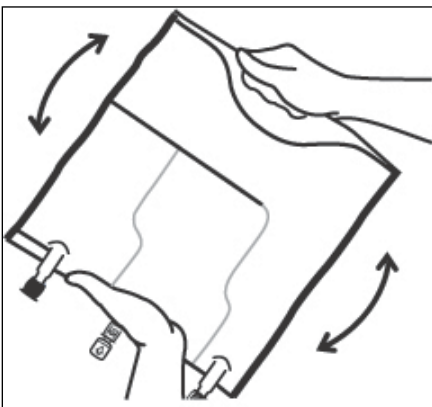
- To remove overwrap, hold the bag horizontally and tear from the notch close to the ports along the upper edge (A).
- Then simply tear the long side, pull off the overwrap and discard it along with the oxygen absorber (B).

2. Mixing



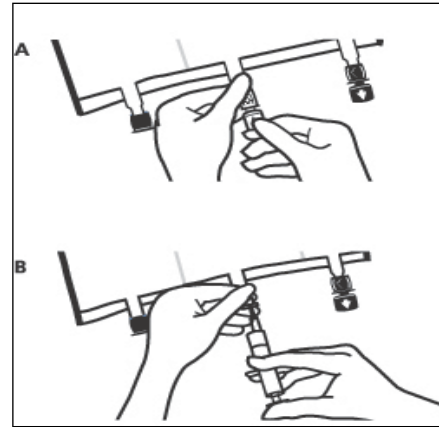
- Place the bag on a flat surface.
- Roll up the bag tightly from the handle side towards the ports, first with the right hand and then applying a constant pressure with the left hand until the vertical seals are broken. The vertical peel seals open due to the pressure of the fluid. The peel seals can also be opened before removing the overwrap.

Please note: The liquids mix easily even though the horizontal seal remains closed.



- Mix the contents of the three chambers by inverting the bag three times until the components are thoroughly mixed.

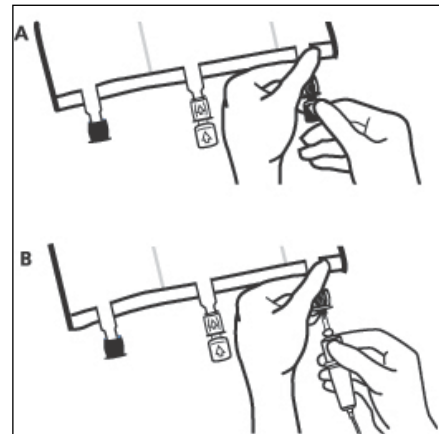
3. Finalising the preparation:



- Place the bag on a flat surface again. If injecting any additives, break off the tamper-evident arrow flag from the white additive port (A).

Please note: The membrane in the additive port is sterile.

- Hold the base of the additive port. Insert the needle, inject the additives (with known compatibility) through the centre of the injection site (B).
- Mix thoroughly between each addition by inverting the bag three times. Use syringes with needles of 18-23 gauge and a length of max. 40 mm.



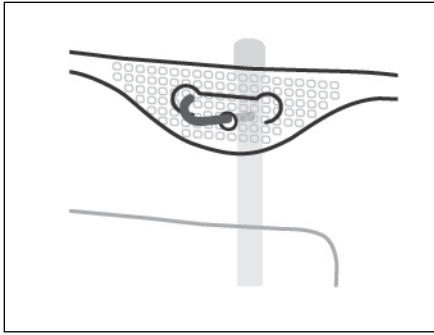
- Immediately before inserting the infusion set, break off the tamper-evident arrow flag from the blue infusion port (A).

Please note: The membrane in the infusion port is sterile.

- Use a non-vented infusion set or close the air-inlet on a vented set.
- Hold the base of the infusion port.
- Push the spike through the infusion port. The spike should be fully inserted to secure it in place.

Please note: The inner part of the infusion port is sterile.

4. Hanging the bag



- Hang the bag up by the hole below the handle.

The medication 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 the dose you have received was too high or SmofKabiven Electrolyte Free was infused too quickly, inform your health care provider immediately. In case of overdose there is a risk of receiving too much fat. This is called “fat overload syndrome”. In these cases the 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 health care provider.

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 medication, SmofKabiven Electrolyte Free can cause side effect in some people.

Common side effects which could occur include nausea, vomiting, gas, high blood sugar (hyperglycemia) and high blood pressure.

If any symptoms of a severe allergic reaction (anaphylaxis) develop, such as fever, shivering, skin rash, hives, flushing, headache, or breathing difficulties the infusion must be stopped and contact your doctor right away.

Serious side effects have been observed during administration of lipid emulsions and are listed in the table below:

| SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM | | | |
|---|-------------------------------------|--------------|---|
| Symptom / effect | Talk with your doctor or pharmacist | | Stop taking drug and call your doctor or pharmacist |
| | Only if severe | In all cases | |
| | | | |

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

Fat overload syndrome:

This might happen when your body has problems using lipids having received too much SmofKabiven Electrolyte Free. It may also happen because of a sudden change in your condition (such as kidney problems or infection). Possible signs include fever, hyperlipidemia, yellowing of the skin and eyes, anemia, trouble in blood clotting, fall in the number of white blood cells and platelets, enlargement of the liver and spleen and coma. All these symptoms will usually disappear when you stop having the infusion.

Let your healthcare provider know if you experience any such side effects.

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

HOW TO STORE IT

Store between 15 °C to 25 °C. Do not freeze. Store bags in overwrap.

Do not use SmofKabiven Electrolyte Free after the expiry date which is printed on the container on the outer packaging (Mm/YYYY). The expiry date refers to the last day of the month.

Once the seals between the chambers have been broken and the product has been mixed, the product should be used immediately

For patient comfort, this medicine should be at room temperature before administration.

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](#);
 - 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 SmofKabiven Electrolyte Free

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Consumer 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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