

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PATIENT MEDICATION INFORMATION

SmofKabiven®

Amino acids with electrolytes, dextrose and lipid injectable emulsion
5.1% & 0.7% / 12.7% / 3.8%; w/v

SmofKabiven® extra Nitrogen

Amino acids with electrolytes, dextrose and lipid injectable emulsion
6.5% & 0.7% / 8.5% / 2.9%; w/v

Read this carefully before you start taking **SmofKabiven** or **SmofKabiven extra Nitrogen** and each time you get a refill. This leaflet is a summary and will not tell you everything about SmofKabiven and SmofKabiven extra Nitrogen. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about SmofKabiven and SmofKabiven extra Nitrogen.

What are SmofKabiven and SmofKabiven extra Nitrogen used for?

SmofKabiven and SmofKabiven extra Nitrogen infusions deliver nutrition directly into your blood, when normal eating is not possible or appropriate for you.

How do SmofKabiven and SmofKabiven extra Nitrogen work?

SmofKabiven and SmofKabiven extra Nitrogen contain a mixture of fats, sugar and amino acids (building blocks for proteins) with salts. These are used to provide energy and nutrients when other forms of feeding are not enough or possible.

Your healthcare professionals may add more salts, vitamins and minerals to SmofKabiven and SmofKabiven extra Nitrogen.

What are the ingredients in SmofKabiven and SmofKabiven extra Nitrogen?

Medicinal ingredients:

Each 100 mL of mixed product for **SmofKabiven** contains:

Amino acids (building blocks for proteins)

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.

Electrolytes (salts)

Sodium acetate trihydrate 170 mg, calcium chloride dihydrate 20 mg, potassium chloride 230 mg, sodium glycerophosphate anhydrous 210 mg, magnesium sulfate heptahydrate 61 mg and zinc sulfate heptahydrate 0.66 mg

Lipids (fats)

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

Dextrose (sugar)

As glucose monohydrate 12.7 g

Each 100 mL of mixed product for **SmofKabiven extra Nitrogen** contains:

Amino acids (building blocks for proteins)

Alanine 920 mg, arginine 790 mg, glycine 720 mg, histidine 200 mg, isoleucine 330 mg, leucine 480 mg, lysine acetate 430 mg, methionine 280 mg, phenylalanine 330 mg, proline 730 mg, serine 430 mg, taurine 65 mg, threonine 290 mg, tryptophan 130 mg, tyrosine 26 mg and valine 410 mg.

Electrolytes (salts)

Sodium acetate trihydrate 160 mg, calcium chloride dihydrate 28 mg, potassium chloride 230 mg, sodium

glycerophosphate anhydrous 230 mg, magnesium sulfate heptahydrate 61 mg and zinc sulfate heptahydrate 0.66 mg

Lipid (fats)

Soybean oil 870 mg, medium-chain triglycerides 870 mg, olive oil 720 mg and fish oil 430 mg

Dextrose (sugar)

As glucose monohydrate 8.5 g

Non-medicinal ingredients in SmofKabiven and SmofKabiven extra Nitrogen:

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

SmofKabiven and SmofKabiven extra Nitrogen come in the following dosage forms:

SmofKabiven and SmofKabiven extra Nitrogen consist of three separate chambers:

- One chamber with a mixture of fats which is:
 - Like milk
 - Consistent
- One chamber with a solution of amino acids (building blocks for proteins) which is:
 - Clear
 - Colourless to slightly yellow
- One chamber with a sugar solution which is:
 - Clear
 - Colourless to slightly yellow

Before use, break the seals between the chambers to mix the components together. The mixture will be:

- Cloudy
- White
- Consistent

Do not use SmofKabiven and SmofKabiven extra Nitrogen if:

- You are allergic (hypersensitive) to fish, eggs, peanuts, soya or any of the ingredients in SmofKabiven and SmofKabiven extra Nitrogen (see **What are the ingredients in SmofKabiven and SmofKabiven extra Nitrogen**)
- You have very high amounts of fats in your blood (severe hyperlipidemia)
- Your liver does not work properly
- Your body cannot use amino acids properly since birth
- You have a severely reduced ability to stop bleeding
- Your kidneys do not work properly and you are not on any type of blood purification (dialysis or hemofiltration)
- You have such a drop in blood pressure that you could die (shock)
- Your blood sugar is out of control
- Your blood has high amounts of any of the salts included in SmofKabiven and SmofKabiven extra Nitrogen
- You have a disease affecting your blood and immune system, called hemophagocytotic syndrome
- You have water build-up in your lungs (acute pulmonary edema)
- You have excess water in your body (hyperhydration)
- You have acute heart failure
- You have an unstable medical condition

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take SmofKabiven or SmofKabiven extra Nitrogen. Talk about any health conditions you may have, including if:

- You have high amounts of fats 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 peanuts.
- You cannot use fats and amino acids (building blocks for proteins) properly because you have:
 - Kidney or liver problems
 - High levels of sugar in your blood (diabetes)
 - An inflamed pancreas (pancreatitis)
 - Low amounts of thyroid hormones (hypothyroidism)
 - A full-body infection (sepsis) that can lead to death
- You have heart problems
- You tend to retain high amounts of salts in your body
- You are pregnant or planning to become pregnant
- You are breast feeding or planning to breastfeed
- You are taking any other medications

Other warnings you should know about:

Severe allergic reaction: If you develop any symptoms of an allergic reaction while taking SmofKabiven or SmofKabiven extra Nitrogen stop the infusion and seek immediate medical help. Symptoms may include:

- Fever
- Shivering
- Sweating
- Headache
- Skin rashes
- Trouble breathing

Fat overload syndrome: This might happen if your body has problems using fats and you received too much SmofKabiven or SmofKabiven extra Nitrogen. It may also happen if there is a sudden change in your condition, such as kidney problems or an infection. Contact your healthcare professional immediately if you experience any of the following symptoms:

- Fever
- High levels of fats in your blood
- Yellowing of the skin and eyes
- A drop in the number of red blood cells
- Difficulty to stop bleeding
- A drop in the number of white blood cells and platelets
- Increase in the size of the liver and spleen
- Coma

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with SmofKabiven and SmofKabiven extra Nitrogen:

- Blood-thinning substances
Inform your doctor if you are taking any blood-thinning substances such as heparins or coumarins (warfarin) that help prevent blood clots.

Soybean oil has a natural content of vitamin K1 which promotes blood clotting. However, the amount of soybean oil in SmofKabiven and SmofKabiven extra Nitrogen is very low and not expected to significantly prevent the blood-thinning effect of coumarins.

- Laboratory tests
SmofKabiven and SmofKabiven extra Nitrogen may interfere with certain laboratory tests. It is important to tell any doctor doing tests that you are using SmofKabiven or SmofKabiven extra Nitrogen.

How to take SmofKabiven and SmofKabiven extra Nitrogen:

- SmofKabiven and SmofKabiven extra Nitrogen can be given:
 - In a hospital
 - In a managed care facility
 - At home
 - under the supervision of a healthcare professional.
 - by yourself, after receiving training and with the agreement of your healthcare team.
- Additional nutrients may be added by pharmacy professionals.
- Use SmofKabiven and SmofKabiven extra Nitrogen only if the mixture is consistent and looks like milk.
- Use only if the bag is not damaged.
- Use germ-free (aseptic) procedures.
- The bag should only be used once.
- Throw away any unused product.

Usual adult dose:

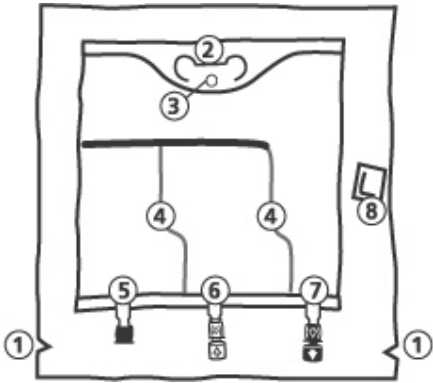
- You will receive your medicine by injection directly into your blood.
- Your healthcare professional will control how much and how fast SmofKabiven and SmofKabiven extra Nitrogen are given, based on your needs and medical condition.
- SmofKabiven and SmofKabiven extra Nitrogen should be given continuously, over 14 to 24 hours.
- Your doctor will monitor your condition and periodically test your blood and urine.

Instructions for use and handling

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

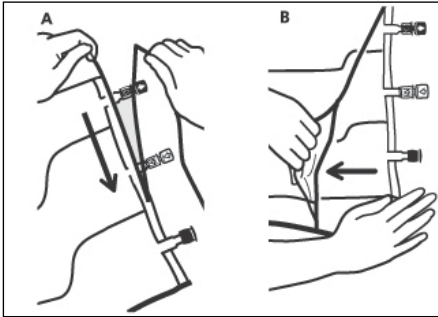
These instructions are only intended as guidelines for product use. Please ask your healthcare professional for detailed instructions on handling.

The bag



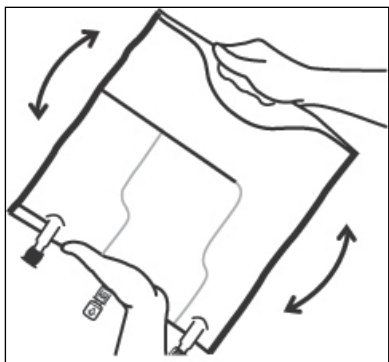
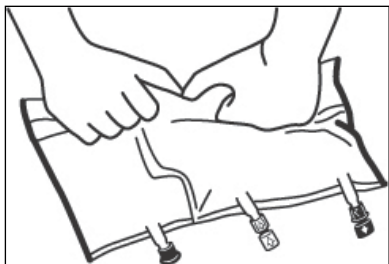
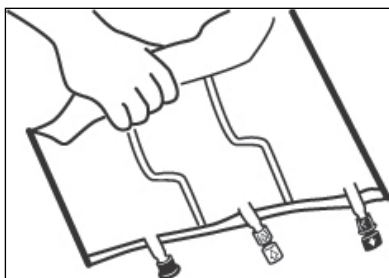
1. Notches in the overwrap
2. Handle
3. Hole for hanging the bag
4. Vertical seals
5. Blind port (only used during manufacturing)
6. WHITE Additive port
7. BLUE Infusion port
8. Oxygen absorber (present between bag and overwrap)

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

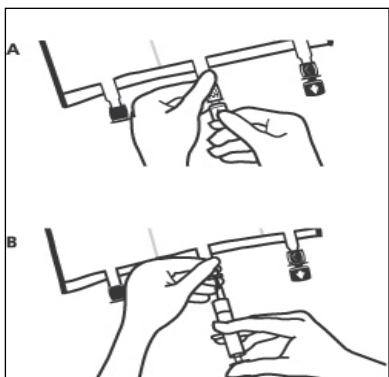


- Place the bag on a clean, flat surface. The text side should be face up and the ports should be pointing away from you.
- Roll up the bag tightly from the handle side towards the ports, first with the right hand and then applying a constant pressure with the left hand until the vertical seals are broken. 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. The entire contents of the bag will be white when mixed.

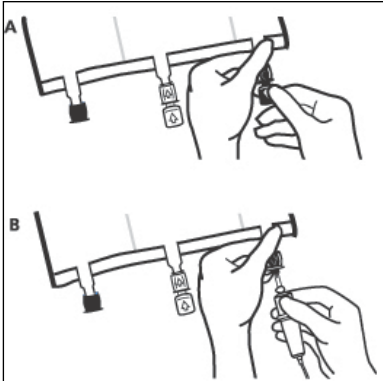
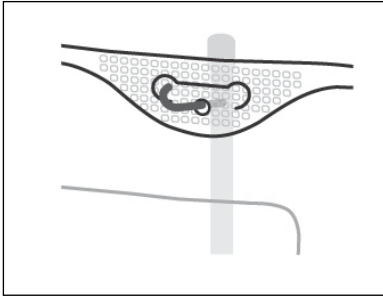
3. Finalising the preparation:



- Place the bag on a clean, 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.

	<ul style="list-style-type: none"> • Immediately before inserting the infusion set, break off the tamper evident arrow flag from the blue infusion port (A). <p>Please note: The membrane in the infusion port is sterile.</p> <ul style="list-style-type: none"> • 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. <p>Please note: The inner part of the infusion port is sterile.</p>
<p>4. Hanging the bag</p> 	<ul style="list-style-type: none"> • Hang the bag up by the hole below the handle.

Overdose:

If you think that the dose you have received was too high or was infused too quickly, inform your healthcare professional 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 “**Other warnings you should know about**” for more information.

If you have any further questions on the use of this product, ask your healthcare professional.

If you think you have taken too much SmofKabiven or SmofKabiven extra Nitrogen, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

What are possible side effects from using SmofKabiven and SmofKabiven extra Nitrogen?

These are not all the possible side effects you may feel when taking SmofKabiven and SmofKabiven extra Nitrogen. If you experience any side effects not listed here, contact your healthcare professional.

Side effects may include:

- Nausea
- Vomiting
- Chills

SmofKabiven and SmofKabiven extra Nitrogen can cause abnormal blood test results. Your healthcare professional will decide when to perform blood tests and will interpret the results.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
RARE Serious allergic reaction: fever, shivering, skin rash, hives, redness, headache, or difficulty breathing			✓
High blood pressure			✓
Increased heart rate			✓
Low blood pressure: dizziness, fainting, lightheadedness May occur when you go from lying or sitting to standing up.			✓
Fat overload syndrome: fever, yellowing of the skin and eyes, coma			✓

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

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.

Storage:

Store below 25 °C. Do not freeze.

Store bags in overwrap. Keep out of reach and sight of children.

Do not use SmofKabiven and SmofKabiven extra Nitrogen after the expiry date which is printed on the bag (YYYY-MM). 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, SmofKabiven and SmofKabiven extra Nitrogen should be at room temperature before administration.

If you want more information about SmofKabiven or SmofKabiven extra Nitrogen:

- 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 (<https://health-products.canada.ca/dpd-bdpp/index-eng.jsp>); the manufacturer's website (<http://www.fresenius-kabi.ca>), or by calling 1-877-821-7724 (toll-free-telephone).

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