Package leaflet: Information for the user

SmofKabiven extra Nitrogen emulsion for infusion

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

Whats is in this leaflet

1. What SmofKabiven extra Nitrogen is and what it is used for
2. What you need to know before you use SmofKabiven extra Nitrogen
3. How to use SmofKabiven extra Nitrogen
4. Possible side effects
5. How to store SmofKabiven extra Nitrogen
6. Contents of the pack and other information

1. What SmofKabiven extra Nitrogen is and what it is used for

SmofKabiven extra Nitrogen is an emulsion for infusion given into your blood by a drip (intravenous infusion). The product contains amino acids (components used to build proteins), glucose (carbohydrates), lipids (fat) and salts (electrolytes) in a plastic bag and can be given to adults and children aged 2 years and above.

A healthcare professional will give you SmofKabiven extra Nitrogen when other forms of feeding are not good enough or have not worked.

2. What you need to know before you use SmofKabiven extra Nitrogen

Do not use SmofKabiven extra Nitrogen
- if you are allergic (hypersensitive) to active substances or any of the other ingredients of this medicine (listed in section 6)
- if you are allergic to fish or egg
- if you are allergic to peanuts or soya you should not use this product. SmofKabiven extra Nitrogen contains soya-bean oil
- if you have too much lipids in the blood (hyperlipidemia)
- if you have serious liver disorder
- if you have blood clotting problems (coagulation disorder)
- if your body has problems using amino acids
- if you have serious kidney disease without access to dialysis
- if you are in acute shock
- if you have too much sugar in your blood (hyperglycaemia) which is uncontrolled
- if you have high blood (serum) levels of the salts (electrolytes) included in SmofKabiven extra Nitrogen
- if you have fluid in the lungs (acute pulmonary oedema)
- if you have too much body fluid (hyperhydrated)
- if you have heart failure that is not treated
- if you have a defect in your blood clotting system (hemophagocytotic syndrome)
- if you are in an unstable condition, such as after serious trauma, uncontrolled diabetes, acute heart attack, stroke, blood clot, metabolic acidosis (a disturbance resulting in too much acid in the blood), serious infection (severe sepsis), coma and if you don’t have enough body fluid (hypotonic dehydration)

- in newborn babies or children under 2 years of age

Warnings and precautions
Talk to your doctor before using SmofKabiven extra Nitrogen if you have:
- kidney problems
- diabetes mellitus
- pancreatitis (inflammation of the pancreas)
- liver problems
- hypothyrodism (thyroid problems)
- sepsis (serious infection)

If you during the infusion get fever, rash, swelling, difficulty in breathing, chills, sweating, nausea or vomiting, tell the healthcare professional immediately because these symptoms might be caused by an allergic reaction or that you have been given too much of the medicine.

Your doctor may regularly need to check your blood for liver function tests and other values.

Children and adolescents
SmofKabiven extra Nitrogen is not meant for newborn babies or children younger than 2 years of age. SmofKabiven extra Nitrogen can be given to children and adolescents from 2 to 16/18 years old.

Other medicines and SmofKabiven extra Nitrogen
Tell your doctor if you are taking, have recently taken or might take any other medicines, even without prescription.

Pregnancy and breast-feeding
Data from using SmofKabiven extra Nitrogen during pregnancy or breast-feeding is lacking. SmofKabiven extra Nitrogen should therefore be given to pregnant or breast-feeding women only if the doctor find it necessary. The use of SmofKabiven extra Nitrogen may be considered during pregnancy and breastfeeding, as advised by your doctor.

Driving and using machines
Not relevant as the medicine is given at the hospital.

3. **How to use** SmofKabiven extra Nitrogen

Always use this medicine exactly as your doctor has told you. Check with your doctor if you are not sure. Your doctor will decide on the dose for you individually depending on your body weight and function. SmofKabiven extra Nitrogen will be given to you by a healthcare professional.

If you use more SmofKabiven extra Nitrogen than you should
It is unlikely that you will receive too much medicine as SmofKabiven extra Nitrogen is given to you by a healthcare professional.

4. **Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Common (may affect up to 1 in 10 people): a slightly raised body temperature.

Uncommon (may affect up to 1 in 100 people): high blood (plasma) levels of compounds from the liver, lack of appetite, nausea, vomiting, chills, dizziness and headache.

Rare (may affect up to 1 in 1,000 people): low or high blood pressure, difficulty in breathing, fast heart beat (tachycardia). Hypersensitivity reactions (that can give symptoms like swelling, fever, fall in blood pressure,

skin rashes, wheals (raised red areas), flushing, headache). Sensations of hot and cold. Paleness. Light blue coloured lips and skin (because of too less oxygen in the blood). Pain in the neck, back, bones, chest and loins.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

For UK - Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

For IE- HPRA Pharmacovigilance
Website: www.hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store SmofKabiven extra Nitrogen

Keep this medicine out of the sight and reach of children.

Store in overpouch. Do not store above 25°C. Do not freeze.

Do not use this medicine after the expiry date which is stated on the label on the bag and box. The expiry date refers to the last day of that month.

6. Contents of the pack and other information

What SmofKabiven extra Nitrogen contains

The active substances are	g per 1000 ml
Alanine	9.2
Arginine	7.9
Glycine	7.2
Histidine	2.0
Isoleucine	3.3
Leucine	4.8
Lysine (as acetate)	4.3
Methionine	2.8
Phenylalanine	3.3
Proline	7.3
Serine	4.3
Taurine	0.65
Threonine	2.9
Tryptophan	1.3
Tyrosine	0.26
Valine	4.1
Calcium chloride (as dihydrate)	0.28
Sodium glycerophosphate (as hydrate)	2.3
Magnesium sulphate (as heptahydrate)	0.61
Potassium chloride	2.3
Sodium acetate (as trihydrate)	1.6

Zinc sulphate (as heptahydrate)	0.0066
Glucose (as monohydrate)	85
Soya-bean oil, refined	8.7
Medium-chain triglycerides	8.7
Olive oil, refined	7.2
Fish oil, rich in omega-3 fatty acids	4.3

The other ingredients are glycerol, purified egg phospholipids, all-rac-α-tocopherol, sodium hydroxide (pH-adjustment), sodium oleate, acetic acid (pH-adjustment), hydrochloric acid (pH-adjustment) and water for injections.

What SmofKabiven extra Nitrogen looks like and contents of the pack

Glucose- and amino acid solutions are clear, colourless or slightly yellow and free from particles. The lipid emulsion is white and homogenous.

Pack sizes:
1 x 506 ml, 6 x 506 ml
1 x 1012 ml, 4 x 1012 ml
1 x 1518 ml, 4 x 1518 ml
1 x 2025 ml, 4 x 2025 ml
1 x 2531 ml, 3 x 2531 ml

Marketing Authorisation Holder and Manufacturer

Manufacturer:

Fresenius Kabi AB,
SE-751 74 Uppsala,
Sweden

Marketing authorisation holder:

For UK:
Fresenius Kabi Limited
Cestrian Court, Eastgate Way
Manor Park, Runcorn
Cheshire, WA7 1NT
United Kingdom

For IRL:
Fresenius Kabi Deutschland GmbH
Else-Kröner-Straße 1,
61352 Bad Homburg v.d.Höhe
Germany

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The following information is intended for healthcare professionals only:

Warnings and precautions for use
To avoid risks associated with too rapid infusion rates, it is recommended to use a continuous and well-controlled infusion, if possible by using a volumetric pump.

Since an increased risk of infection is associated with the use of any central vein, strict aseptic precautions should be taken to avoid any contamination especially during catheter insertion and manipulations.

Serum glucose, electrolytes and osmolarity as well as fluid balance, acid-base status and liver and enzyme tests should be monitored.

Any sign or symptom of anaphylactic reaction (such as fever, shivering, rash or dyspnoea) should lead to immediate interruption of the infusion.

SmofKabiven extra Nitrogen should not be given simultaneously with blood in the same infusion set due to the risk of pseudoagglutination.

Method of administration
Intravenous use, infusion into a central vein.

To provide total parenteral nutrition, trace elements, vitamins and possibly electrolytes (taking into account the electrolytes already present in SmofKabiven extra Nitrogen) should be added to SmofKabiven extra Nitrogen according to the patients need.

Posology

Adults

Dosage:
The dosage range of 13-31 ml SmofKabiven extra Nitrogen /kg bw/day corresponds to 0.14-0.32 g nitrogen/kg bw/day (0.85-2.0 g amino acids/kg bw/day) and 12-28 kcal/kg bw/day of total energy (8-19 kcal/kg bw/day of non-protein energy).

Infusion rate:
The maximum infusion rate for glucose is 0.25 g/kg bw/h, for amino acids 0.1 g/kg bw/h, and for lipids 0.15 g/kg bw/h.

The infusion rate should not exceed 1.5 ml/kg bw/h (corresponding to 0.13 g glucose, 0.10 g amino acids, and 0.04 g lipids/kg bw/h). The recommended infusion period is 14-24 hours.

Maximum daily dose:
The maximum daily dose varies with the clinical condition of the patient and may even change from day to day. The recommended maximum daily dose is 31 ml/kg bw/day.

Paediatric population

Children (2-11 years)

Dosage:
The dose up to 31 ml/kg bw/day should be regularly adjusted to the requirements of the paediatric patient that varies more than in adult patients.

Infusion rate:
The recommended maximum infusion rate is 1.8 ml/kg bw/h (corresponding to 0.12 g amino acids/kg/h, 0.15 g/glucose/kg/h and 0.05 g lipids/kg/h). At the recommended maximum infusion rate, do not use an infusion period longer than 17 hours, except in exceptional cases and with careful monitoring.
The recommended infusion period is 12-24 hours.

Maximum daily dose:
The maximum daily dose varies with the clinical condition of the patient and may even change from day to day. The recommended maximum daily dose is 31 ml/kg bw/day.

Adolescents (12-16/18 years)

In adolescents, SmofKabiven extra Nitrogen can be used as in adults.

Precautions for disposal

Do not use if package is damaged.

Use only if the amino acid and glucose solutions are clear and colourless or slightly yellow and the lipid emulsion is white and homogenous. The contents of the three separate chambers have to be mixed before use, and before any additions are made via the additive port.
After separation of the peelable seals the bag should be inverted on a number of occasions to ensure a homogenous mixture, which does not show any evidence of phase separation.

For single use only. Any unused solution remaining after infusion should be discarded.

Compatibility
Compatibility data are available with the named branded products Dipeptiven, Addamel N (known as Additrace in UK and IE)/Addaven (known as Additrace N in IE), Glycophos (known as Sodium Glycerophosphate in UK), Addiphos, Vitlipid N Adult/Infant and Solivito N in defined amounts and generics of electrolytes in defined concentrations. When making electrolyte additions, the amounts already present in the bag should be taken into account to meet the clinical needs of the patient. Generated data supports additions to the activated bag according to the summary table below:

Compatibility range stable for 7 days, i.e., 6 days storage at 2-8°C followed by 24 hours at 20-25°C.

	Units	**Maximal total contents**				
SmofKabiven extra Nitrogen bag size	ml	506	1012	1518	2025	2531
Additive		**Volume**				
Dipeptiven	ml	0 - 150	0 - 300	0 - 300	0 - 300	0 - 300
Addamel N (known as Additrace in UK and IE)/Addaven (known as Additrace N in IE)	ml	0 - 10	0 - 20	0 - 20	0 - 20	0 - 20
Solivito N	Vial(s)	0 - 1	0 - 2	0 - 2	0 - 2	0 - 2
Vitlipid N Adult/Infant	ml	0 - 10	0 - 20	0 - 20	0 - 20	0 - 20
Electrolyte limits[1]		**Concentration**				
Sodium	mmol/l	≤ 150	≤ 150	≤ 150	≤ 150	≤ 150
Potassium	mmol/l	≤ 150	≤ 150	≤ 150	≤ 150	≤ 150
Calcium	mmol/l	≤ 5	≤ 5	≤ 5	≤ 5	≤ 5
Magnesium	mmol/l	≤ 5	≤ 5	≤ 5	≤ 5	≤ 5
Phosphate inorganic (Addiphos) OR Phosphate organic (Glycophos (known as Sodium Glycerophosphate in UK))	mmol/l	≤ 15 ≤ 30	≤ 15 ≤ 30	≤ 15 ≤ 30	≤ 15 ≤ 30	≤ 15 ≤ 30
Zinc	mmol/l	≤ 0.2	≤ 0.2	≤ 0.2	≤ 0.2	≤ 0.2
Selenium	µmol/l	≤ 2	≤ 2	≤ 2	≤ 2	≤ 2

[1.] *includes amounts from all products*

Note: This table is intended to indicate compatibility. It is not a dosing guideline.

For branded products, before prescribing refer to national approved prescribing information.

Compatibility with further additives and the storage time of different admixtures will be available upon request.

Additions should be made aseptically.

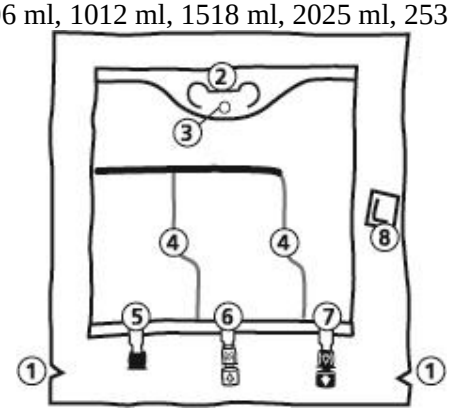
Shelf-life after mixing *the chambers of the bag*
Chemical and physical in-use stability of the mixed three chamber bag has been demonstrated for 48 hours at 20- 25°C. From a microbiological point of view the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2-8°C unless mixing has taken place in controlled and validated aseptic conditions.

Shelf-life after mixing with additives

Physico-chemical in-use stability of the mixed three chamber bag with additives has been demonstrated for up to 7 days, i.e., 6 days at 2-8°C followed by 24 hours at 20-25°C, including duration of administration. From a microbiological point of view, the product should be used immediately when additions have been made. If not used immediately, the in-use storage time and conditions prior to use are the responsibility of the user. The storage time should normally not be longer than 24 hours at 2-8°C unless addition of supplements has taken place in controlled and validated aseptic conditions.

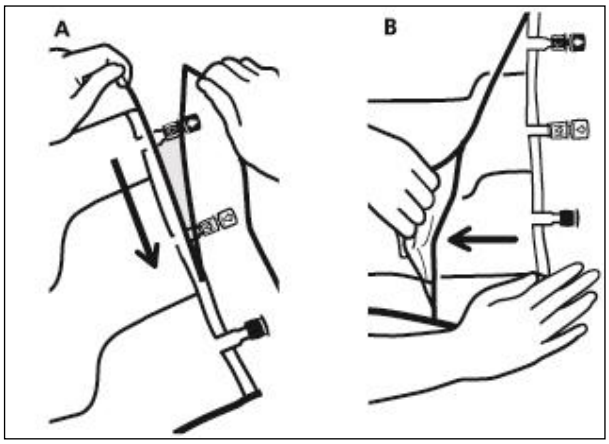
Instructions for use SmofKabiven extra Nitrogen

The bag
506 ml, 1012 ml, 1518 ml, 2025 ml, 2531 ml



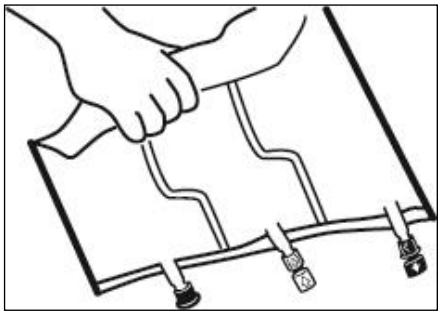
1. Notches in the overpouch
2. Handle
3. Hole for hanging the bag
4. Peelable seals
5. Blind port (only used during manufacturing)
6. Additive port
7. Infusion port
8. Oxygen absorber

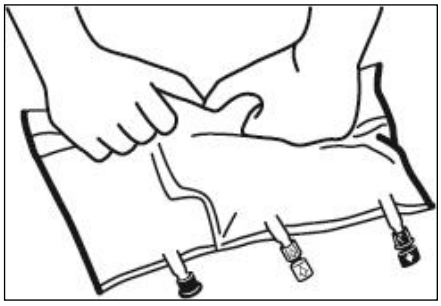
1. Removal of overpouch

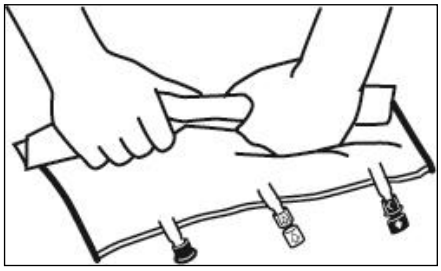


- To remove overpouch, hold the bag horizontally and tear from the notch close to the ports along the upper edge (A).
- Then simply tear the long side, pull off the overpouch and discard it along with the oxygen absorber (B).

2. Mixing



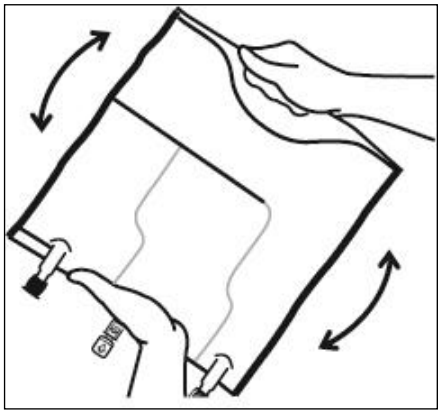




- Place the bag on a flat surface.
- Roll up the bag tightly from the handle side towards the ports, firstly with the right hand and then applying a constant pressure with the left hand until the vertical seals are broken. The vertical peel seals open due to the pressure of the fl uid. The peel seals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

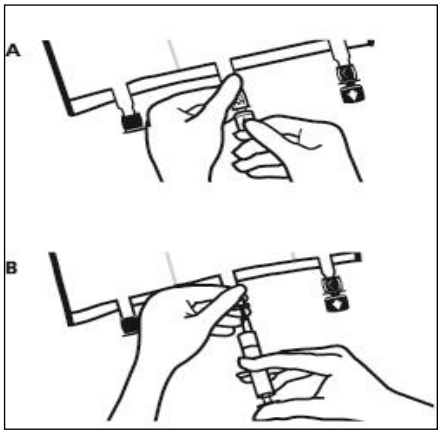
Please note: The liquids mix easily although the horizontal seal remains closed.

506 ml, 1012 ml, 1518 ml, 2025 ml, 2531 ml



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

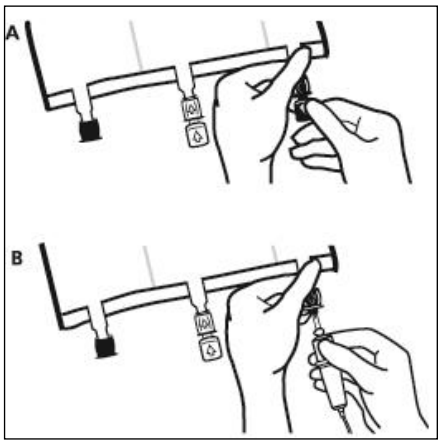
3. Finalising the preparation:



- Place the bag on a flat surface again. Shortly before injecting the 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.



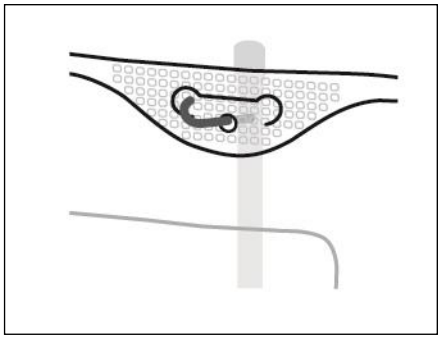
- Shortly before inserting the infusion set, break off the tamper evident arrow flag from the blue infusion port (A).

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. Hooking up the bag



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