Package leaflet: Information for the user

SmofKabiven Nutribase 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 Nutribase is and what it is used for

SmofKabiven Nutribase 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 Nutribase when other forms of feeding are not good enough or have not worked.

2. What you need to know before you use SmofKabiven Nutribase

Do not use SmofKabiven Nutribase
- if you are allergic (hypersensitive) to the 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 Nutribase contains soya-bean oil
- if you have too much lipids in the blood (hyperlipidemia)
- if you have serious liver disorder
- if you have serious blood clotting problems (serious coagulation disorder)
- if your body has congenital problems with using amino acids
- if you have serious kidney disease without access to dialysis or hemofiltration
- if you are in acute shock (severe blood circulation disorder)
- if you have too much sugar in your blood (hyperglycaemia) which is uncontrolled
- if you have high blood (serum) levels of the salts (electrolytes) that are included in SmofKabiven Nutribase
- 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 and children under 2 years of age

Warnings and precautions
Talk to your doctor before using SmofKabiven Nutribase 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 Nutribase is not meant for newborn babies or children younger than 2 years of age. SmofKabiven Nutribase can be given to children from 2 to 18 years of age.

Other medicines and SmofKabiven Nutribase
Tell your doctor if you are taking, have recently taken or might take any other medicines.

Pregnancy and breastfeeding
If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before using this medicine.

Data from using SmofKabiven Nutribase during pregnancy is lacking. SmofKabiven Nutribase should therefore be given to pregnant women only if the doctor finds it necessary. The use of SmofKabiven Nutribase may be considered during pregnancy, as advised by your doctor.

There is no data available of exposure in breast-feeding women.
Components and metabolites of parenteral nutrition like SmofKabiven Nutribase are excreted in human milk. Parenteral nutrition may become necessary during breastfeeding. SmofKabiven Nutribase should only be given to breast-feeding women after your doctor has considered the potential risks and benefits.

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

3. How to use SmofKabiven Nutribase

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 Nutribase will be given to you by a healthcare professional.

If you use more SmofKabiven Nutribase than you should
It is unlikely that you will receive too much medicine as SmofKabiven Nutribase 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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

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

Ireland
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 Nutribase

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 Nutribase contains

The active substances are	*g per 1000 ml*
Alanine	4.7
Arginine	4.1
Glycine	3.7
Histidine	1.0
Isoleucine	1.7
Leucine	2.5
Lysine (as acetate)	2.2
Methionine	1.5
Phenylalanine	1.7
Proline	3.8
Serine	2.2
Taurine	0.34
Threonine	1.5
Tryptophan	0.68
Tyrosine	0.14
Valine	2.1

Calcium chloride (as dihydrate)	0.19
Sodium glycerophosphate (as hydrate)	1.4
Magnesium sulphate (as heptahydrate)	0.41
Potassium chloride	1.5
Sodium acetate (as trihydrate)	1.1
Zinc sulphate (as heptahydrate)	0.0044
Glucose (as monohydrate)	89
Soya-bean oil, refined	12
Medium-chain triglycerides	12
Olive oil, refined	9.8
Fish oil, rich in omega-3 fatty acids	5.9

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

What SmofKabiven Nutribase looks like and contents of the pack

SmofKabiven Nutribase, emulsion for infusion consists of a three-chamber bag system where one chamber contains glucose solution, one contains amino acid solution and one contains lipid emulsion. 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 1026 ml, 4 x 1026 ml
1 x 1539 ml, 4 x 1539 ml
1 x 2052 ml, 4 x 2052 ml
1 x 2565 ml, 3 x 2565 ml

Marketing Authorisation Holder
UK
Fresenius Kabi Ltd
Cestrian Court
Eastgate Way, Manor Park
Runcorn, Cheshire, WA7 1NT
United Kingdom

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

Manufacturer
Fresenius Kabi AB, Rapsgatan 7, 751 74 Uppsala, Sweden

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The following information is intended for healthcare professionals only (for more detailed information please, see the Summary of Product Characteristics):

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 Nutribase 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 Nutribase) should be provided in addition to SmofKabiven Nutribase according to the patient's need. Mixing *within* the SmofKabiven Nutribase bag should only be done where compatibility has been shown, see section Special precautions for disposal and other handling.

Posology

Adults

Dosage:
The dosage range of 18-40 ml SmofKabiven Nutribase/kg bw/day corresponds to 0.10-0.22 g nitrogen/kg bw/day (0.6-1.4 g amino acids/kg bw/day) and 16-35 kcal/kg bw/day of total energy (13-30 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 2.8 ml/kg bw/h (corresponding to 0.25 g glucose, 0.09 g amino acids, and 0.11 g lipids/kg bw/h). The recommended infusion period is 6.5-24 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 40 ml/kg bw/day.

Paediatric population

Children (2-11 years)

Dosage:
The dose up to 40 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 infusion rate should not exceed 3.4 ml/kg bw/h (corresponding to 0.30 g glucose, 0.12 g amino acids, and 0.13 g lipids/kg bw/h).

The recommended infusion period is 5-24 hours. At the recommended maximum infusion rate, do not use an infusion period longer than 11 hours 45 minutes, except in exceptional cases and with careful monitoring.

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 40 ml/kg bw/day.

Adolescents (12-18 years)
In adolescents, SmofKabiven Nutribase can be used as in adults.

Special precautions for disposal and other handling

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 three times to ensure a homogenous mixture, which does not show any evidence of phase separation.

For single use only. Any unused medicinal product remaining after infusion must be discarded.

Any unused medicinal product or waste material should be disposed in accordance with local requirement

Compatibility
The compatibility table below shows possible additions with the named branded products Dipeptiven, Addaven, Vitalipid N Adult/Infant and Soluvit N (lyophilized). Generated data supports additions to the activated bag according to the summary table below:

Maximal total contents	
SmofKabiven Nutribase bag size	1026 mL, 1539 mL, 2052 mL and 2565 mL
Additive	**Volume**
Dipeptiven	0 - 300 mL
Addaven	0 - 10 mL
Soluvit N	0 - 1 vial
Vitalipid N Adult/Infant	0 - 10 mL

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

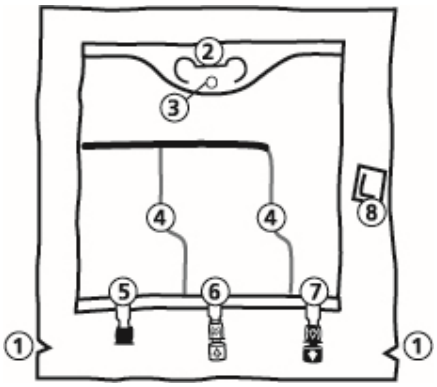
Additions should be made aseptically.

Shelf-life after mixing
Chemical and physical in-use stability of the mixed three chamber bag has been demonstrated for 36 hours at 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.

Shelf life after mixing with compatible medicinal products
From a microbiological point of view, the product should be used immediately when additions have been made.

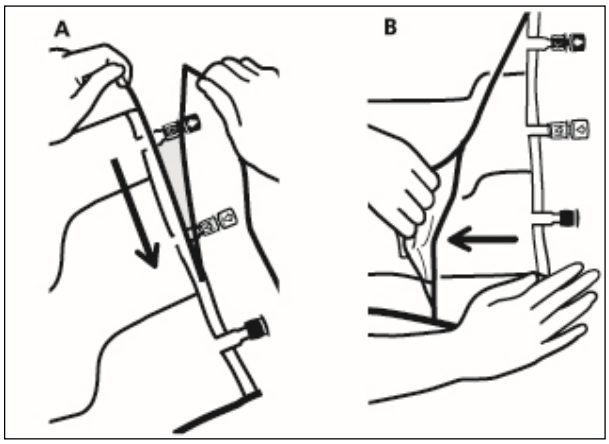
Instructions for use *SmofKabiven Nutribase*

The bag



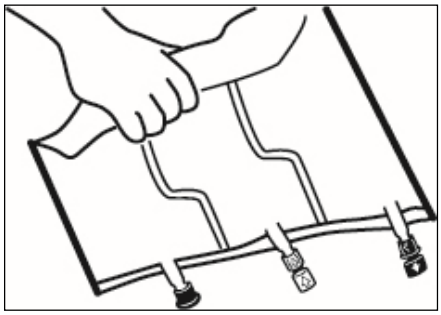
1. Notches in the overpouch
2. Handle
3. Hole for hanging the bag
4. Peelable seals
5. Blind port (only used during manufacturing)
6. Additive port
7. Infusion port
8. Oxygen absorber

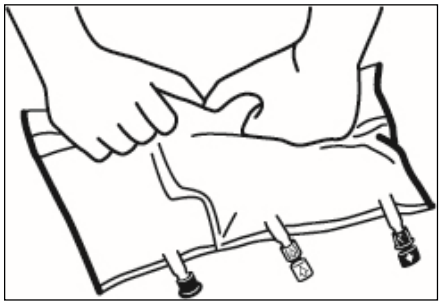
1. Removal of overpouch

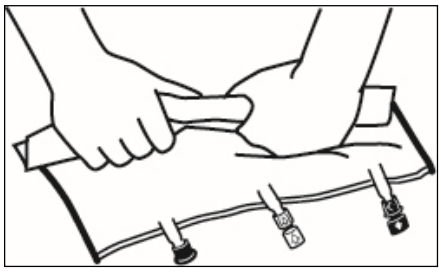


- To remove overpouch, hold the bag horizontally and tear from the notch close to the ports along the upper edge (A).
- Then simply tear the long side, pull off the overpouch and discard it along with the oxygen absorber (B).

2. Mixing

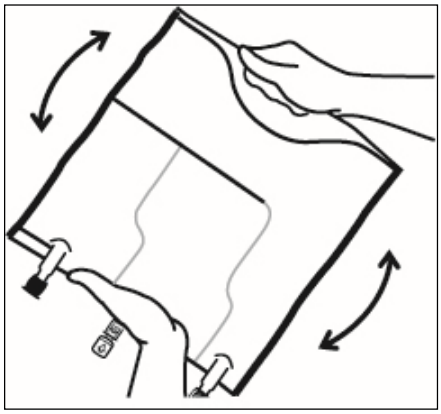






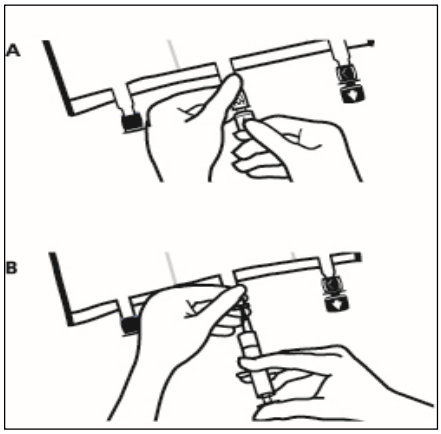
- Place the bag on a flat surface.
- Roll up the bag tightly from the handle side towards the ports, firstly with the right hand and then applying a constant pressure with the left hand until the vertical seals are broken. The vertical peel seals open due to the pressure of the fluid. The peel seals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

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



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

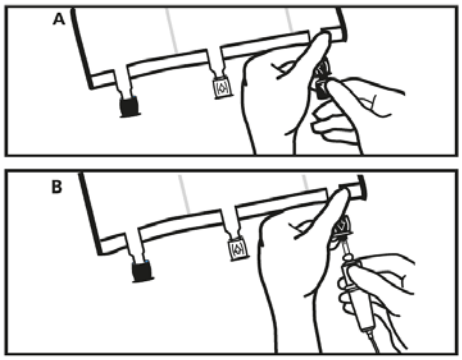
3. Finalising the preparation:



- Place the bag on a flat surface again. 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.



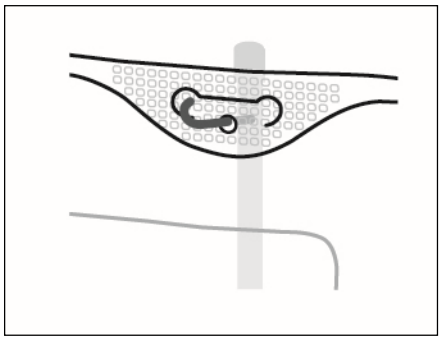
- Shortly before inserting the infusion set, break off the tamper evident arrow flag from the blue infusion port (A).

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.