PACKAGE LEAFLET: INFORMATION FOR THE USER

SmofKabiven Central
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.

What is in this leaflet:

1. What SmofKabiven Central is and what it is used for

SmofKabiven Central 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), fat (lipids) 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 Central when other forms of feeding are not good enough or have not worked.

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

Do not use SmofKabiven Central:
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 Central contains soybean oil
- if you have too much lipids in the blood (hyperlipidaemia)
- if you have serious liver disorder
- if you have blood clotting problems (coagulation disorders)
- 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 Central
- if you have fluid in the lungs (acute pulmonary oedema)
- if you have too much body fluid (hyperhydration)
- if you have heart failure that is not treated
- if you have a defect in your blood clotting system (haemophagocytotic syndrome)
- if you are in an unstable condition, such as after serious trauma, uncontrolled diabetes, acute heart attack, stroke, blood clot (embolism), 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 children under 2 years of age

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

If during the infusion you 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 Central is not meant for newborn babies or children younger than 2 years old. SmofKabiven can be given to children from 2 to 16/18 years old.

Other medicines and SmofKabiven Central
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 Central during pregnancy or breast-feeding is lacking. SmofKabiven Central should therefore be given to pregnant or breast-feeding women only if the doctor finds it necessary. The use of SmofKabiven Central 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 Central

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 Central will be given to you by a healthcare professional.

If you use more SmofKabiven Central than you should
It is unlikely that you will receive too much medicine as SmofKabiven Central 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 - You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard

For Ireland - You can report directly via;
HPRA Pharmacovigilance
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
e-mail: medsafety@hpra.ie

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

5. How to store SmofKabiven Central

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 Central contains

The active substances are	*g per 1000 ml*
Alanine	7.1
Arginine	6.1

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 Central 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 Central) should be added to SmofKabiven Central according to the patients need.

Posology

Adults

Dosage:
The dosage range of 13-31 ml SmofKabiven/kg bw/day will provide 0.6-1.6 g amino acids/kg bw/day (corresponds to 0.10-0.25 g nitrogen/kg bw/day) and 14-35 kcal/kg bw/day of total energy (12-27 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 2.0 ml/kg bw/h (corresponding to 0.25 g glucose, 0.10 g amino acids, and 0.08 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 35 ml/kg bw/day.

Paediatric population

Children (2-11 years)

Dosage:
The dose up to 35 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 2.4 ml/kg bw/h (corresponding to 0.12 g amino acids/kg/h, 0.30 g/glucose/kg/h and 0.09 g lipids/kg/h). At the recommended maximum infusion rate, do not use an infusion period longer than 14 hours 30 minutes, 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 35 ml/kg bw/day.

Adolescents (12-16/18 years)
In adolescents, SmofKabiven 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
Only medicinal or nutrition solutions for which compatibility has been documented may be added to SmofKabiven Central. Compatibility for different additives and the storage time of the different admixtures will be available upon request.
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 additives
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.

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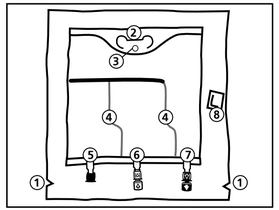
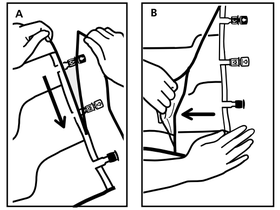
Instructions for use

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).

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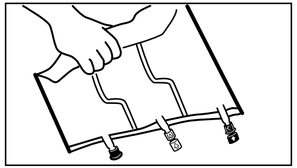
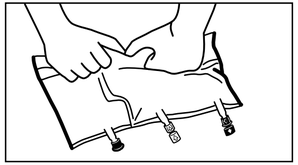
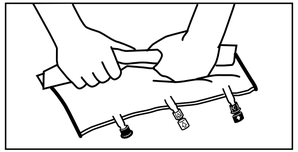
2. Mixing

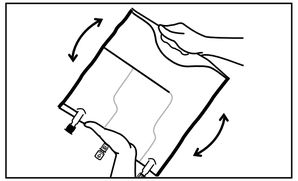






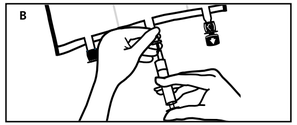
- Place the bag on a flat surface.
- Roll up the bag tightly from the handle side towards the ports, firstly with the right hand and then applying a constant pressure with the left hand until the vertical seals are broken. The vertical peel seals open due to the pressure of the fluid. The peel seals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

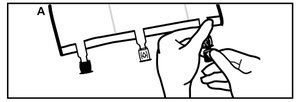
3. Finalising the preparation:

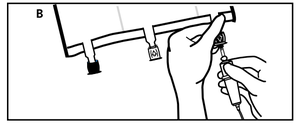


- Place the bag on a flat surface again. Shortly before injecting the additives, break off the tamper-evident arrow flag from the white additive port (A).

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.





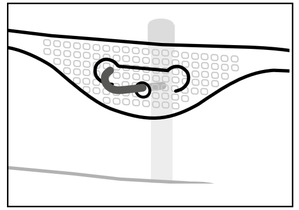
- Shortly before inserting the infusion set, break off the tamper evident arrow flag from the blue infusion port (A).

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. Hanging up the bag



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

Glycine	5.6
Histidine	1.5
Isoleucine	2.5
Leucine	3.8
Lysine (as acetate)	3.4
Methionine	2.2
Phenylalanine	2.6
Proline	5.7
Serine	3.3
Taurine	0.5
Threonine	2.2
Tryptophan	1.0
Tyrosine	0.20
Valine	3.1
Calcium chloride (as dihydrate)	0.28
Sodium glycerophosphate (as hydrate)	2.1
Magnesium sulphate (as heptahydrate)	0.61
Potassium chloride	2.3
Sodium acetate (as trihydrate)	1.7
Zinc sulphate (as heptahydrate)	0.0066
Glucose (as monohydrate)	127
Soybean oil, refined	11.4
Medium-chain triglycerides	11.4
Olive oil, refined	9.5
Fish oil, rich in omega-3-fatty acids	5.7

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

What SmofKabiven Central looks like and contents of the pack

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

Pack sizes:
1 x 493 ml, 6 x 493 ml
1 x 986 ml, 4 x 986 ml
1 x 1477 ml, 4 x 1477 ml
1 x 1970 ml, 4 x 1970 ml
1 x 2463 ml, 3 x 2463 ml

Marketing Authorisation Holder and Manufacturer

MAH for UK:
Fresenius Kabi Ltd
Cestrian Court
Eastgate Way
Manor Park
Runcorn
Cheshire
WA7 1NT
United Kingdom

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

Manufacturer:
Fresenius Kabi AB, SE-751 74 Uppsala, Sweden

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