APPROVED PROFESSIONAL INFORMATION

SCHEDULING STATUS **S4**

1. NAME OF THE MEDICINE

SMOFKABIVEN emulsion for infusion

Strength

Amino acid solution with electrolytes

Glucose 42 %

Lipid emulsion

(see section 2)

Pharmaceutical form

Emulsion for infusion

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

SMOFKABIVEN consists of a three-chamber bag system including:

1. Amino acid solution with electrolytes
2. Glucose 42 %
3. Lipid emulsion

	493 ml	**986 ml**	**1 477 ml**	**1 970 ml**	**2 463 ml**	**Per 1000 ml**
Amino acid solution with electrolytes	250 ml	500 ml	750 ml	1 000 ml	1250 ml	508 ml
Glucose 42%	149 ml	298 ml	446 ml	595 ml	744 ml	302 ml
Lipid emulsion	94 ml	188 ml	281 ml	375 ml	469 ml	190 ml

This corresponds to the following total compositions:

Active ingredients	**493 ml**	**986 ml**	**1 477ml**	**1 970 ml**	**2 463 ml**	**Per 1 000 ml**
Alanine	3,5 g	7,0 g	10,5 g	14,0 g	17,5 g	7,1 g
Arginine	3,0 g	6,0 g	9,0 g	12,0 g	15,0 g	6,1 g

Glycine	2,8 g	5,5 g	8,2 g	11,0 g	13,8 g	5,6 g
Histidine	0,8 g	1,5 g	2,2 g	3,0 g	3,7 g	1,5 g
Isoleucine	1,3 g	2,5 g	3,8 g	5,0 g	6,2 g	2,5 g
Leucine	1,9 g	3,7 g	5,6 g	7,4 g	9,4 g	3,8 g
Lysine (as acetate)	1,7 g	3,3 g	5,0 g	6,6 g	8,4 g	3,4 g
Methionine	1,1 g	2,2 g	3,2 g	4,3 g	5,4 g	2,2 g
Phenylalanine	1,3 g	2,6 g	3,8 g	5,1 g	6,4 g	2,6 g
Proline	2,8 g	5,6 g	8,4 g	11,2 g	14,0 g	5,7 g
Serine	1,6 g	3,2 g	4,9 g	6,5 g	8,1 g	3,3 g
Taurine	0,25 g	0,50 g	0,75 g	1,0 g	1,2 g	0,5 g
Threonine	1,1 g	2,2 g	3,3 g	4,4 g	5,4 g	2,2 g
Tryptophan	0,5 g	1,0 g	1,5 g	2,0 g	2,5 g	1,0 g
Tyrosine	0,10 g	0,20 g	0,30 g	0,40 g	0,49 g	0,20 g
Valine	1,6 g	3,1 g	4,6 g	6,2 g	7,6 g	3,1 g
Calcium chloride (as dihydrate)	0,14 g	0,28 g	0,42 g	0,56 g	0,69 g	0,28 g
Sodium glycerophosphate (as hydrate)	1,1 g	2,1 g	3,1 g	4,2 g	5,2 g	2,1 g
Magnesium sulphate (as heptahydrate)	0,30 g	0,60 g	0,90 g	1,2 g	1,5 g	0,61 g
Potassium chloride	1,1 g	2,2 g	3,4 g	4,5 g	5,7 g	2,3 g
Sodium acetate (as trihydrate)	0,9 g	1,7 g	2,6 g	3,4 g	4,2 g	1,7 g
Zinc sulphate (as heptahydrate)	0,0033 g	0,0065 g	0,0097 g	0,013 g	0,016 g	0,0066 g
Glucose (as monohydrate)	63 g	125 g	187 g	250 g	313 g	127 g
Soya-bean oil, refined	5,6 g	11,3 g	16,9 g	22,5 g	28,1 g	11,4 g
Medium-chain triglycerides	5,6 g	11,3 g	16,9 g	22,5 g	28,1 g	11,4 g
Olive oil, refined	4,7 g	9,4 g	14,1 g	18,8 g	23,4 g	9,5 g
Fish oil, rich in omega-3-acids	2,8 g	5,6 g	8,4 g	11,3 g	14,0 g	5,7 g

Corresponding to:	**493 ml**	**986 ml**	**1 477 ml**	**1 970 ml**	**2 463 ml**	**Per 1 000 ml**
•Amino acids	25 g	50 g	75 g	100 g	125 g	51 g
•Nitrogen	4 g	8 g	12 g	16 g	20 g	8 g
•Electrolytes						
- sodium	20 mmol	40 mmol	60 mmol	80 mmol	100 mmol	41 mmol
- potassium	15 mmol	30 mmol	45 mmol	60 mmol	74 mmol	30 mmol
- magnesium	2,5 mmol	5,0 mmol	7,5 mmol	10 mmol	12 mmol	5,1 mmol
- calcium	1,3 mmol	2,5 mmol	3,8 mmol	5,0 mmol	6,2 mmol	2,5 mmol
- phosphate[1]	6 mmol	12 mmol	19 mmol	25 mmol	31 mmol	13 mmol
- zinc	0,02 mmol	0,04 mmol	0,06 mmol	0,08 mmol	0,1 mmol	0,04 mmol
- sulphate	2,5 mmol	5,0 mmol	7,5 mmol	10 mmol	13 mmol	5,1 mmol
- chloride	18 mmol	35 mmol	52 mmol	70 mmol	89 mmol	36 mmol
- acetate	52 mmol	104 mmol	157 mmol	209 mmol	261 mmol	106 mmol
•Carbohydrates						
- Glucose (anhydrous)	63 g	125 g	187 g	250 g	313 g	127 g
•Lipids	19 g	38 g	56 g	75 g	94 g	38 g
•Energy content						
- total (approx.)	550 kcal 2,3 MJ	1100 kcal 4,6 MJ	1600 kcal 6,7 MJ	2200 kcal 9,2 MJ	2700 kcal 11,3 MJ	1100 kcal 4,6 MJ
- non protein (approx.)	450 kcal 1,9 MJ	900 kcal 3,8 MJ	1300 kcal 5,4 MJ	1800 kcal 7,5 MJ	2200 kcal 9,2 MJ	900kcal 3,8 MJ

[1] Contribution to both lipid emulsion and amino acid solution

Contains sugar as Glucose (127 g per 1 000 ml)

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Emulsion for infusion

Three-chamber bag consisting of amino acid solution 10 %, glucose solution 42 % and lipid emulsion corresponding to SMOFlipid 20 %.

Amino acid solution with electrolytes (Aminoven 10 %):

A clear solution, colourless to slightly yellow and practically free from particles, in a three-chamber bag.

Glucose 42 %:

Clear; not more intensely coloured than Y6/BY6

Smoflipid 20 %:

A white emulsion.

Mixed three-chamber bag:

A white emulsion in an open/mixed three-chamber bag.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Parenteral nutrition for adults and children aged 2 years and above when oral or enteral nutrition is impossible, insufficient or contraindicated.

4.2 Posology and method of administration

Posology

The appearance of SMOFKABIVEN after mixing the 3 chambers is a white emulsion.

The patient's ability to eliminate fat and metabolise nitrogen and glucose, and the nutritional requirements should govern the dosage and infusion rate (see section 4.4).

The dose should be individualised with regard to the patient's clinical condition and body weight (bw), nutritional and energy requirements, adjusting dosage based upon additional oral/enteral intake.

The nitrogen requirements for maintenance of body protein mass depend on the patient's condition (e.g. nutritional state and degree of catabolic stress or anabolism).

Adults

The requirements are 0,10 to 0,15 g nitrogen/kg bw/day (0,6 to 0,9 g amino acids/kg bw/day) in the normal nutritional state or in conditions with mild catabolic stress. In patients with moderate to high metabolic stress with or without malnutrition, the requirements are in the range of 0,15 to 0,25 g nitrogen/kg bw/day (0,9 to 1,6 g amino acids/kg bw/day). In some very special conditions (e.g. burns or marked anabolism) the nitrogen need may be even higher.

Dosage:

The dosage range of 13 ml to 31 ml SMOFKABIVEN/kg bw/day corresponds to 0,10 g to 0,25 g nitrogen/kg bw/day (0,6 to 1,6 g amino acids/kg bw/day) and 14 to 35 kcal/kg bw/day of total energy (12 to 27 kcal/kg bw/day of non-protein energy). This covers the need of the majority of the patients. In obese patients the dose should be based on the estimated ideal weight.

Infusion rate

The maximum infusion rate for glucose is 0,25 g/kg bw/h, for amino acid 0,1 g/kg bw/h and for fat 0,15 g/kgbw/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 fat/kg bw/h). The recommended infusion period is 14 to 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.

The recommended maximum daily dose of 35 ml/kg bw/day will provide 0,28 g nitrogen/kg bw/day (corresponding to 1,8 g amino acids/kg bw/day), 4,5 g glucose/kg bw/day, 1,33 g fat/kg bw/day and a total energy of 39 kcal/kg bw/day (corresponding to 31 kcal/kg bw/day of non-protein energy).

Paediatric population

Children (2 to 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 to 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.

The recommended maximum daily dose of 35 ml/kg bw/day will provide 1,8 g amino acids/kg bw/day (corresponding to 0,28 g nitrogen/kg bw/day), 4,5 g glucose/kg bw/day, 1,33

g lipids/kg bw/day and a total energy content of 39 kcal/kg bw/day (corresponding to 31 kcal/kg bw/day of non-protein energy).

Adolescents (12 to 16/18 years)

In adolescents, SMOFKABIVEN can be used as in adults.

Method of administration

Intravenous use, infusion into a central vein.

The five different package sizes of SMOFKABIVEN are intended for patients with high, moderately increased or basal nutritional requirements. To provide total parenteral nutrition, trace elements, vitamins and possibly electrolytes (taking into account the electrolytes already present in SMOFKABIVEN) should be added to SMOFKABIVEN according to the patients need.

4.3 Contraindications

- Hypersensitivity to fish, egg, soya or peanut protein or to any of the active substances or excipients (listed in section 6.1).
- Severe hyperlipidemia.
- Severe liver insufficiency.
- Severe blood coagulation disorders.
- Congenital errors of amino acid metabolism.
- Severe renal insufficiency without access to haemofiltration or dialysis.
- Acute shock.
- Hyperglycaemia.
- Cardiac failure.
- Pathologically elevated serum levels of any of the included electrolytes.

- General contraindications to infusion therapy: acute pulmonary oedema, hyperhydration, and decompensated cardiac insufficiency.
- Haemophagocytotic syndrome.
- Unstable conditions (e.g. severe post-traumatic conditions, uncompensated diabetes mellitus, pulmonary embolism, stroke, embolism, metabolic acidosis, severe sepsis, hypotonic dehydration and hyperosmolar coma).
- Infants and children under 2 years of age.

4.4 Special warnings and special precautions for use

SMOFKABIVEN should not be given simultaneously with blood in the same infusion set due to the risk of pseudo-agglutination.

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 during catheter insertion and manipulation.

Fat overload syndrome

The capacity to eliminate fat is individual and should therefore be monitored. This is done by checking the triglyceride levels. The concentration of triglycerides in serum should not exceed 4 mmol/l during infusion. An overdose or impaired capacity to eliminate triglycerides may lead to fat overload syndrome (see section 4.8).

SMOFKABIVEN should be given with caution in conditions of impaired lipid metabolism, which may occur in patients with renal failure, diabetes mellitus, pancreatitis, impaired liver function, hypothyroidism and sepsis.

Hypersensitivity reactions

SMOFKABIVEN contains soy-bean oil, fish oil and egg phospholipids, which may cause allergic reactions. Cross allergic reaction has been observed between soy-bean and peanuts. Any sign or symptom of anaphylactic reaction (such as fever, shivering, rash or dyspnoea) should lead to immediate interruption of the infusion.

Excess of glucose infusion

In patients with hyperglycaemia, administration of exogenous insulin might be necessary.

Electrolyte and fluid balance

Disturbances of the electrolyte and fluid balance (e.g. abnormally high or low serum levels of the electrolytes) should be corrected before starting the infusion.

SMOFKABIVEN should be given with caution to patients with a tendency towards electrolyte retention. Special clinical monitoring is required at the beginning of any intravenous infusion. Should any abnormal sign occur the infusion should be stopped.

The amount of individual electrolytes to be added is governed by the clinical condition of the patient and by frequent monitoring of serum levels.

General precautions

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

Blood cell count and coagulation should be monitored when fat is given for a longer period.

In patients with renal insufficiency, the phosphate and potassium intake should be carefully controlled to prevent hyperphosphataemia and hyperkalaemia.

Parenteral nutrition should be given with caution in lactic acidosis, insufficient cellular oxygen supply and increased serum osmolarity.

The fat content of SMOFKABIVEN may interfere with certain laboratory measurements (e.g. bilirubin, lactate dehydrogenase, oxygen saturation, haemoglobin) if blood is sampled before

fat has been adequately cleared from the bloodstream. Fat is cleared after a fat-free interval of 5 to 6 hours in most patients.

Intravenous infusion of amino acids is accompanied by increased urinary excretion of the trace elements, in particular copper and zinc. This should be considered in the dosing of trace elements, especially during long-term intravenous nutrition. Amounts of zinc administered with SMOFKABIVEN should be taken into account.

In malnourished patients, initiation of parenteral nutrition can precipitate fluid shifts resulting in pulmonary oedema and congestive heart failure as well as a decrease in the serum concentration of potassium, phosphorus, magnesium and water-soluble vitamins. These changes can occur within 24 to 48 hours, therefore careful and slow initiation of parenteral nutrition is recommended in this patient group, together with close monitoring and appropriate adjustments of fluid, electrolytes, minerals and vitamins.

Paediatric population

Due to composition of the amino acid solution in SMOFKABIVEN it is not suitable for the use in newborns or infants below 2 years of age.

There is at present no clinical experience of the use of SMOFKABIVEN in children (age 2 years to 16/18 years).

At present there is no experience of treatment with the lipid component of SMOFKABIVEN for more than 14 days.

4.5 Interactions with other medicines and other forms of interaction

Some medicines, like insulin, may interfere with the body's lipase system. This kind of interaction however seems to be of limited clinical importance.

Heparin given in clinical doses causes a transient release of lipoprotein lipase into the circulation. This may result initially in increased plasma lipolysis followed by a transient decrease in triglyceride clearance.

Soy-bean oil has a natural content of vitamin K1. However, the low concentration in SMOFKABIVEN is not expected to significantly influence the coagulation process in patients treated with coumarin derivatives.

4.6 Fertility, pregnancy and lactation

Pregnancy and Breastfeeding

Safety has not been demonstrated in pregnancy and lactation.

There are no data available on exposure of SMOFKABIVEN in pregnant or breastfeeding women.

Fertility

There are no studies available on reproductive toxicity in animals.

4.7 Effects on ability to drive and use machines

SMOFKABIVEN has no influence on the ability to drive and use machines.

4.8 Undesirable effects

a) Tabulated list of adverse reactions

	Frequent	Less frequent
Immune system disorders		Hypersensitivity-reactions (e.g. anaphylactic or anaphylactoid reactions, skin rash, urticaria, flush, headache), heat or cold sensation, paleness, cyanosis, pain in the neck, back, chest, bones and loins
Cardiac disorders		Tachycardia
Respiratory, thoracic and mediastinal disorders		Dyspnoea
Gastrointestinal disorders		Lack of appetite, nausea, vomiting
Metabolism and nutrition disorders		Elevated plasma levels of liver enzymes

Vascular disorders		Hypotension, hypertension
General disorders and administration site conditions	Increase in body temperature	Chills, dizziness, headache

b) Description of selected adverse reactions

Should these side-effects occur the infusion of SMOFKABIVEN should be stopped or, if necessary, continued at a reduced dosage.

Fat overload syndrome

Possible signs of metabolic overload should be observed. The cause may be genetic (individually different metabolism) or the fat metabolism may be affected by ongoing or previous illnesses. This syndrome may also appear during severe hypertriglyceridaemia, even at the recommended infusion rate, and in association with a sudden change in the patient's clinical condition, such as renal function impairment or infection. The fat overload syndrome is characterised by hyperlipidaemia, fever, fat infiltration, hepatomegaly with or without icterus, splenomegaly, anaemia, leucopenia, thrombocytopenia, coagulation disorder, haemolysis and reticulocytosis, abnormal liver function tests and coma. The symptoms are usually reversible if the infusion of the lipid emulsion is discontinued.

Excess of amino acid infusion

As with other amino acid solutions, the amino acid content in SMOFKABIVEN may cause undesirable effects when the recommended infusion rate is exceeded. These effects are nausea, vomiting, shivering and sweating. Amino acid infusion may also cause a rise in body temperature. With an impaired renal function, increased levels of nitrogen containing metabolites (e.g. creatinine, urea) may occur.

Excess of glucose infusion

If the glucose clearance capacity of the patient is exceeded, hyperglycaemia will develop.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the “6.04 Adverse Drug Reactions Reporting Form”, found online under SAHPRA’s publications: https://www.sahpra.org.za/Publications/Index/8

4.9 Overdose

See **section 4.8, "Fat overload syndrome"**, **"Excess of amino acid infusion"** and **"Excess of glucose infusion"**.

If symptoms of overdose of fat or amino acids occur, the infusion should be slowed down or discontinued. There is no specific antidote for overdose. Emergency procedures should be general supportive measures, with particular attention to respiratory and cardiovascular systems. Close biochemical monitoring would be essential and specific abnormalities treated appropriately.

If hyperglycaemia occurs, it should be treated according to the clinical situation either by appropriate insulin administration and/or adjustment of the infusion rate.

Additionally, overdose might cause fluid overload, electrolyte imbalances and hyperosmolality.

In some rare serious cases, haemodialysis, haemofiltration or haemo-diafiltration may be considered.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

A.32.2 Other

Pharmacotherapeutic group: Solutions for parenteral nutrition

ATC code: B05BA10

Lipid emulsion

The lipid emulsion of SMOFKABIVEN is composed of soya-bean oil, medium-chain triglycerides, olive oil and fish oil. The lipid emulsion has the particle size and biological properties similar to that of endogenous chylomicrons. The constituents of the lipid emulsion have except for their energy contents, their own pharmacodynamic properties.

Soya-bean oil has a high content of essential fatty acids. The omega-6 fatty acid linoleic acid is the most abundant (approx. 55 to 60 %). Alpha-linolenic acid, an omega-3 fatty acid, constitutes about 8 %. This part of SMOFKABIVEN provides the necessary amount of essential fatty acids.

Medium-chain fatty acids are rapidly oxidised and provide the body with a form of immediately available energy.

Olive oil mainly provides energy in the form of mono-unsaturated fatty acids, which are much less prone to peroxidation than the corresponding amount of poly-unsaturated fatty acids.

Fish oil is characterised by a high content of eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA). DHA is an important structural component of cell membranes, whereas EPA is a precursor of eicosanoids as prostaglandins, thromboxanes and leucotrienes.

Amino acids and electrolytes

The amino acids, constituents of protein in ordinary food, are utilised for tissue protein synthesis and any surplus is channeled to a number of metabolic pathways. Studies have shown a thermogenic effect of amino acid infusion.

Glucose

Glucose should have no pharmacodynamic effects apart from contributing to maintain or replete the normal nutritional status.

5.2 Pharmacokinetic properties

Lipid emulsion

The individual triglycerides in the lipid emulsion have different clearance rate but the lipid emulsion as a mixture is eliminated faster than long chain triglycerides (LCT). Olive oil has

the slowest clearance rate of the components (somewhat slower than LCT) and medium-chain triglycerides (MCT) the fastest. Fish oil in a mixture with LCT has the same clearance rate as LCT alone.

Amino acids and electrolytes

The principal pharmacokinetic properties of the infused amino acids and electrolytes are essentially the same as for amino acids and electrolytes supplied by ordinary food. However, the amino acids of dietary protein first enter the portal vein and then the systemic circulation, while intravenously infused amino acids reach the systemic circulation directly.

Glucose

The pharmacokinetic properties of infused glucose are essentially the same as those of glucose supplied by ordinary food.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Amino acid solution with electrolytes (Aminoven 10 %)

- Acetic acid glacial
- Water for injection

Glucose 42 %

- Hydrochloric acid
- Water for injection

Lipid emulsion (SMOFlipid 20 %)

- all-rac-α-Tocopherol
- Purified egg phospholipids
- Glycerol, anhydrous
- Sodium oleate
- Sodium hydroxide

• Water for injections

6.2 Incompatibilities

SMOFKABIVEN may only be mixed with other medicines for which compatibility has been documented.

6.3 Shelf life

Shelf life of the medicine as packaged for sale

24 Months

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 SMOFKABIVEN 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 to 8 °C.

Shelf life after mixing with additives

From a microbiological point of view, SMOFKABIVEN 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 and should normally not be longer than 24 hours at 2 to 8 °C.

6.4 Special precautions for storage

Store at or below 25 °C.

Do not freeze. Store in over pouch.

Shelf life after mixing: See section 6.3.

Shelf life after mixing with additives: See section 6.3.

6.5 Nature and contents of container

SMOFKABIVEN is packed into a three-chamber inner bag made of Biofine, a high barrier overpouch and an oxygen absorber. The inner bag is filled with amino acid solution corresponding to Aminoven 10 %, Glucose 42 % and SMOFlipid 20 % in separate chambers divided by peelable seals.

Pack sizes:

Biofine bags:

1 x 493 ml, 4 x 493 ml

1 X 986 ml, 4 X 986 ml

1 X 1 477 ml, 4 X 1 477 ml

1 X 1 970 ml, 4 X 1 970 ml

1 X 2 463 ml, 3 X 2 463

6.6 Special precautions for disposal and other handling

Instructions for use

Do not use if the 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 must 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.

Compatibility

Only medicines or nutrition solutions for which compatibility has been documented may be added to SMOFKABIVEN. Compatibility for different additives and the storage time of the different admixtures will be available upon request.

Addition should be made aseptically.

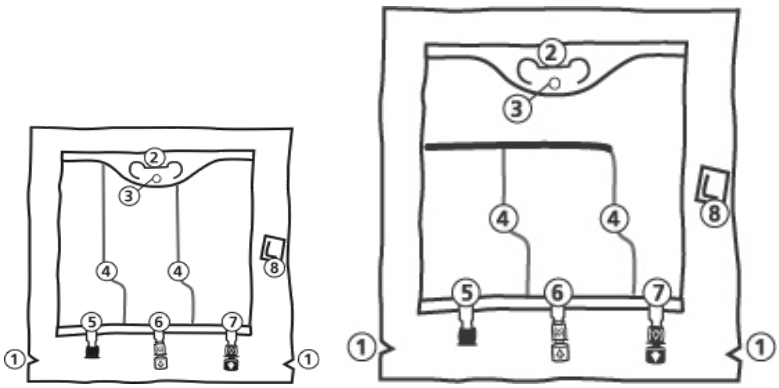
For single use only. Any mixture remaining after infusion must be discarded.

Any unused medicine or waste material should be disposed in accordance with local requirement.

Instructions for use of SMOFKABIVEN

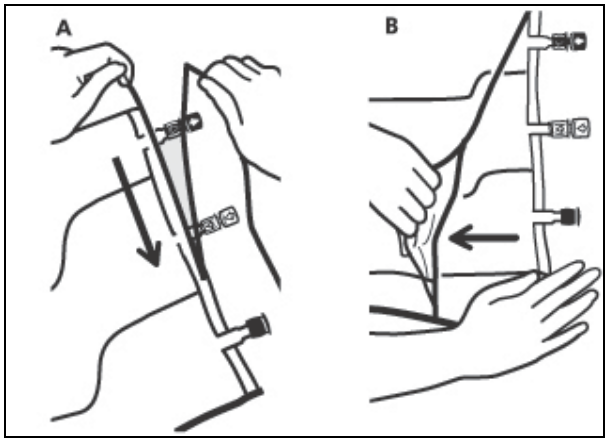
The bag

493 ml 986 ml, 1477 ml, 1970 ml, 2463 ml



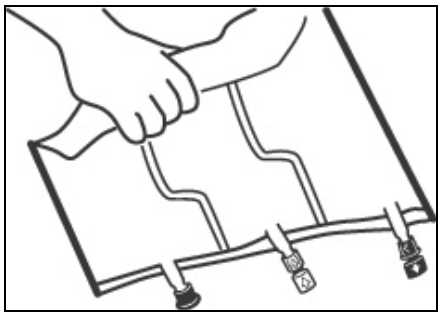
1. Notches in the overpouch
2. Handle
3. Hole for hanging the bag
4. Peelable seals
5. Blind port (only used during Manufacturing)
6. Additive port
7. Infusion port
8. Oxygen absorber

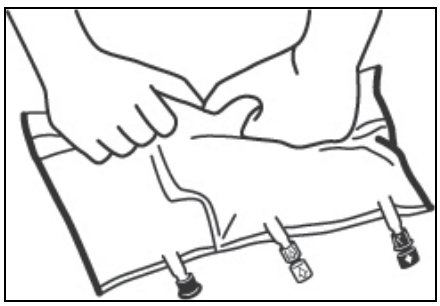
1. Removal of overpouch

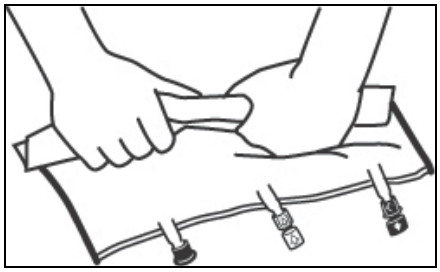


- To remove overpouch, hold the bag horizontally and tear from the notch close to the ports along the upper edge (A).
- Then simply tear the long side, pull off the overpouch and discard it along with the oxygen absorber (B).

2. Mixing



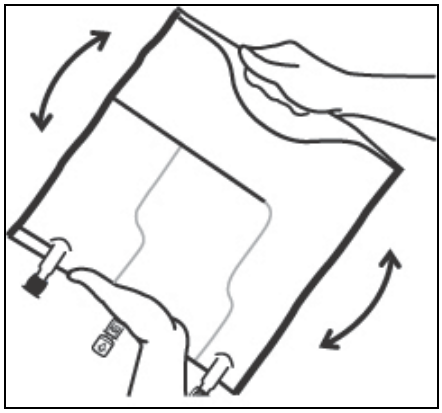




- Place the bag on a flat surface.
- Roll up the bag tightly from the handle side towards the ports, firstly with the right hand and then applying a constant pressure with the left hand until the vertical seals are broken. The vertical peel seals open due to the pressure of the fluid. The peel seals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

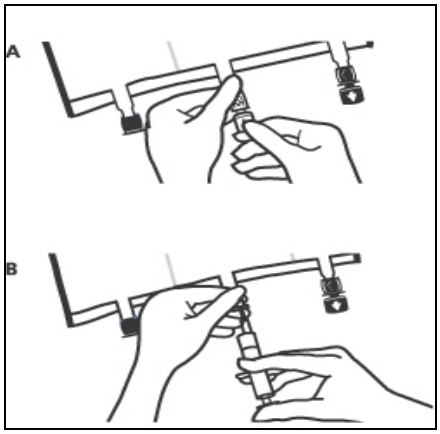
Please note: The liquids mix easily although the horizontal seal remains closed.

493 ml, 986 ml, 1477 ml, 1970 ml, 2463 ml



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

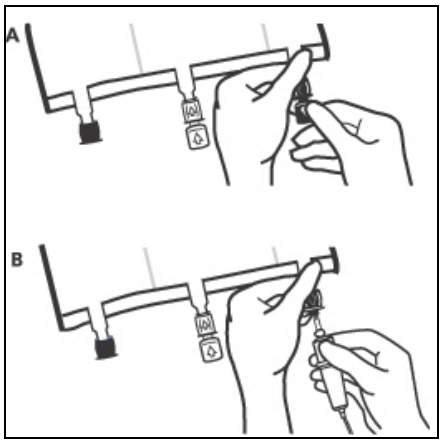
3. Finalising the preparation:



- 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 to 23 gauge and a length of max. 40 mm.



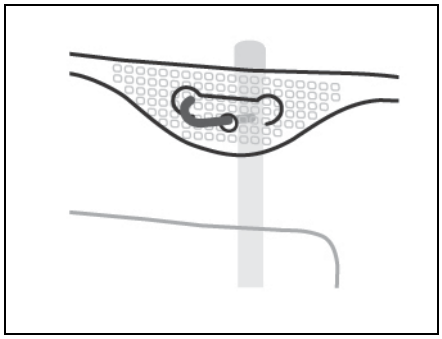
- Shortly before inserting the infusion set, break off the tamper evident arrow flag from the blue infusion port (A).

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.

7. HOLDER OF CERTIFICATE OF REGISTRATION

FRESENIUS KABI SOUTH AFRICA (PTY) LIMITED

Stand 7, Growthpoint Park

2 Tonetti Street

Halfway House 1685

8. REGISTRATION NUMBER

46/32.2/0518

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

27 September 2022

10. DATE OF REVISION OF THE TEXT