FRESENIUS KABI

caring for life

SmofKabiven® Central

(Amino acids, electrolytes, glucose, lipid emulsion)

Parenteral Nutrition

Multi Chamber Bag Compendium

Prescribing information can be found at the back of the compendium

Our Multi Chamber bag range

- SmofKabiven® Peripheral (Amino acids, electrolytes, glucose, lipid emulsion)
- SmofKabiven® Central (Amino acids, electrolytes, glucose, lipid emulsion)
- SmofKabiven® Electrolyte Free Central (Amino acids, glucose, lipid emulsion)
- SmofKabiven® extra Nitrogen (Amino acids, electrolytes, glucose, lipid emulsion)
- SmofKabiven® extra Nitrogen Electrolyte free (Amino acids, glucose, lipid emulsion)
- SmofKabiven® Low Osmo Peripheral (Amino acids, electrolytes, glucose, lipid emulsion)
- Kabiven® Peripheral (Amino acids, electrolytes, glucose, lipid emulsion)
- Kabiven® (Amino acids, electrolytes, glucose, lipid emulsion)

Total Bag Contents

Regimen	Shelf Life*	Route **	Volume ml	Total Kcal	Non-Protein Kcal	g/ Nitrogen	g/ Glucose	g/Fat	Na mmols	K mmols	Ca mmols	Mg mmols	PO4 mmols ***	Zinc mmols
SmofKabiven® Peripheral 9.8	2 yrs	P	1904	1300	1100	9.8	135	54	48	36	3	6	15.6	0.05
SmofKabiven® Central 4	2 yrs	C	493	550	450	4	63	19	20	15	1.3	2.5	6	0.02
SmofKabiven® Central 8	2 yrs	C	986	1100	900	8	125	38	40	30	2.5	5	12	0.04
SmofKabiven® Electrolyte Free Central 8	2 yrs	C	986	1100	900	8	125	38	nil	nil	nil	nil	2.8	nil
SmofKabiven® Central 12	2 yrs	C	1477	1600	1300	12	187	56	60	45	3.8	7.5	19	0.06
SmofKabiven® Electrolyte Free Central 12	2 yrs	C	1477	1600	1300	12	187	56	nil	nil	nil	nil	4.2	nil
SmofKabiven® Central 16	2 yrs	C	1970	2200	1800	16	250	75	80	60	5	10	25	0.08
SmofKabiven® Electrolyte Free Central 16	2 yrs	C	1970	2200	1800	16	250	75	nil	nil	nil	nil	5.6	nil

For further information please see the Summaries of Product Characteristics.

* Before mixing chambers
** Route: C = Central. P = Peripheral or Central
*** Including any amount provided by the lipid source

Total Bag Contents

Regimen	Shelf Life*	Route **	Volume ml	Total Kcal	Non-Protein Kcal	g/ Nitrogen	g/ Glucose	g/Fat	Na mmols	K mmols	Ca mmols	Mg mmols	PO4 mmols ***	Zinc mmols
SmofKabiven® extra Nitrogen 1012ml	2 yrs	C	1012	900	635	10.6	85.7	29.2	41.3	30.9	2.6	5.2	12.9	0.04
SmofKabiven® extra Nitrogen 1518ml	2 yrs	C	1518	1350	952	15.9	129	43.8	61.9	46.4	3.9	7.7	19.3	0.06
SmofKabiven® extra Nitrogen 2025ml	2 yrs	C	2025	1800	1270	21.2	171	58.4	82.6	61.9	5.2	10.3	25.8	0.08
SmofKabiven® extra Nitrogen Electrolyte free 1012ml	2 yrs	C	1012	900	635	10.6	85.7	29.2	nil	nil	nil	nil	2.2	nil
SmofKabiven® extra Nitrogen Electrolyte free 1518ml	2 yrs	C	1518	1350	952	15.9	129	43.8	nil	nil	nil	nil	3.3	nil
SmofKabiven® extra Nitrogen Electrolyte free 2025ml	2 yrs	C	2025	1800	1270	21.2	171	58.4	nil	nil	nil	nil	4.4	nil

For further information please see the Summaries of Product Characteristics.

* Before mixing chambers
** Route: C = Central. P = Peripheral or Central
*** Including any amount provided by the lipid source.

Total Bag Contents

Regimen	Shelf Life*	Route **	Volume ml	Total Kcal	Non-Protein Kcal	g/ Nitrogen	g/ Glucose	g/Fat	Na mmols	K mmols	Ca mmols	Mg mmols	PO4 mmols ***	Zinc mmols
SmofKabiven® Low Osmo Peripheral 1400ml	2 yrs	P	1400	1000	872	5.6	95.1	49	28	21	1.8	3.5	10	0.028
SmofKabiven® Low Osmo Peripheral 1950ml	2 yrs	P	1950	1400	1215	7.81	132	68.2	39	29	2.5	4.9	15	0.039
SmofKabiven® Low Osmo Peripheral 2500ml	2 yrs	P	2500	1800	1559	10	170	87.6	50	38	3.1	6.3	19	0.05

For further information please see the Summaries of Product Characteristics.

* Before mixing chambers
** Route: C = Central. P = Peripheral or Central
*** Including any amount provided by the lipid source.

Total Bag Contents

Regimen	Shelf Life*	Route **	Volume ml	Total Kcal	Non-Protein Kcal	g/ Nitrogen	g/ Glucose	g/Fat	Na mmols	K mmols	Ca mmols	Mg mmols	PO4 mmols ***
Kabiven® Peripheral 5	2 yrs	P	1440	1000	900	5.4	97	51	32	24	2	4	11
Kabiven® Peripheral 7	2 yrs	P	1920	1400	1200	7.2	130	68	43	32	2.7	5.3	14
Kabiven® Peripheral 9	2 yrs	P	2400	1700	1500	9	162	85	53	40	3.3	6.7	18
Kabiven® 8	2 yrs	C	1540	1400	1200	8.1	150	60	48	36	3	6	15
Kabiven® 11	2 yrs	C	2053	1900	1600	10.8	200	80	64	48	4	8	20
Kabiven® 14	2 yrs	C	2566	2300	2000	13.5	250	100	80	60	5	10	25

For further information please see the Summaries of Product Characteristics.

* Before mixing chambers
** Route: C = Central. P = Peripheral or Central
*** Including any amount provided by the lipid source.

Ordering Information

Item Description	Product Code	Case Quantity
SmofKabiven® Peripheral 9.8gN	831912220	4
SmofKabiven® Central 4gN	831917220	6
SmofKabiven® Central 8gN	831901220	4
SmofKabiven® EF Central 8gN	831905220	4
SmofKabiven® Central 12gN	831902220	4
SmofKabiven® EF Central 12gN	831906220	4
SmofKabiven® Central 16gN	831903220	4
SmofKabiven® EF Central 16gN	831907220	4

EF = Electrolyte Free

Item Description	Product Code	Case Quantity
SmofKabiven® extra Nitrogen 1012ml	833061220	4
SmofKabiven® extra Nitrogen 1518ml	833079220	4
SmofKabiven® extra Nitrogen 2025ml	833087220	4
SmofKabiven® extra Nitrogen EF 1012ml	833020220	4
SmofKabiven® extra Nitrogen EF 1518ml	833004220	4
SmofKabiven® extra Nitrogen EF 2025ml	833012220	4

Item Description	Product Code	Case Quantity
SmofKabiven® Low Osmo Peripheral 1400ml	833111220	4
SmofKabiven® Low Osmo Peripheral 1950ml	833129220	4
SmofKabiven® Low Osmo Peripheral 2500ml	833137220	3

Ordering Information

Item Description	Product Code	Case Quantity
Kabiven® Peripheral 5gN	831231220	4
Kabiven® Peripheral 7gN	831232220	4
Kabiven® Peripheral 9gN	831233220	3
Kabiven® 8gN	831221220	4
Kabiven® 11gN	831222221	4
Kabiven® 14gN	831223220	3

Item Description	Product Code	Case Quantity
3 Chamber Bag Red Covers Large (Free of Charge)	3CB Bag	order singles
Protective caps FMCB Red (additive Port, Free of Charge)	831042420	50 caps per bag.

Multi Chamber Bag Range – Mixing Guidelines

NB: The 2 vertical peel seals need to be broken. The horizontal peel seal does **NOT** need to be broken.

1. The 3 Chamber Bag

Remove the 3 chamber bag from the box and place the bag on a flat surface. Roll the bag from the handle end towards the end with the three ports.

2. Opening the 2 vertical seals which separate the 3 chambers

(a) Grab the top right hand side of the bag with your right hand and roll the bag right to left as far as the horizontal seal. (Remember you do not need to open the horizontal seal).

(b) Grab the top left hand side of the bag with your left hand and roll the bag in a downward motion applying pressure with both hands. Use the pressure of the fluid to break the seal. The vertical peel seal will begin to open.

(c) Roll the bag a little further with your left hand and apply pressure left to right, the vertical seal will open fully.

(d) Roll the bag further with your left hand towards the right vertical seal while applying pressure. When the right vertical seal opens the fat (white) solution will flow into the bag.

3. Mixing thoroughly

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

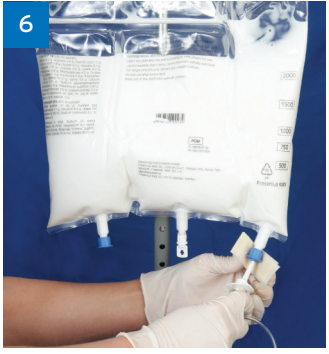
4. Removal of the overpouch

To remove the overpouch tear the overpouch at the port end. There are notches on either side of the bag, begin to tear from one notch to the other side. When you have done this simply tear the long sides of the overpouch and remove and discard the overpouch along with the oxygen absorber. The overpouch can also be removed before breaking the peel seals.

5. Hanging the Bag

Hang the bag up by the hole below the handle.

6. Inserting the infusion set



Break off the arrow flag from the blue infusion port. Please note: The membrane of 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.

Prescribing information - SmofKabiven® Peripheral emulsion for infusion.

Consult the Summary of Product Characteristics for full information. Additional information is available on request. **Active Ingredients:** *1904ml bag* Amino acid solution with electrolytes 600ml, Glucose 13% 1036ml, Lipid emulsion 268ml - corresponding to: Soya-bean oil, (refined) 16.1g, Medium-chain triglycerides 16.1g, Olive oil, refined 13.4g, Fish oil, rich in omega-3 fatty acids 8.0g, Glucose (as monohydrate) 135g, Alanine 8.4g, Arginine 7.2g, Glycine 6.6g, Histidine 1.8g, Isoleucine 3.0g, Leucine 4.4g, Lysine (as acetate) 4.0g, Methionine 2.6g, Phenylalanine 3.1g, Proline 6.7g, Serine 3.9g, Taurine 0.6g, Threonine 2.6g, Tryptophan 1.2g, Tyrosine 0.24g, Valine 3.7g, Calcium chloride (as dihydrate) 0.34g, Sodium Glycerophosphate (as hydrate) 2.5g, Magnesium sulphate (as heptahydrate) 0.72g, Potassium chloride 2.7g, Sodium acetate (as trihydrate) 2.0g, Zinc sulphate (as heptahydrate) 0.008g **Indications:** Parenteral nutrition for adults and children aged 2 years and above when oral or enteral nutrition is impossible, insufficient or contraindicated. **Dosage and administration:** Intravenous infusion into a peripheral or central vein. The dose should be individualised to the patient's clinical condition, body weight (bw) and nutritional requirements. *Adults* – The dose range of 20 – 40ml/kg bw/day covers the needs of the majority of patients. In obese patients the dose should be based on the estimated ideal weight. The recommended maximum daily dose is 40ml/kg bw/day. The infusion rate should not exceed 3.0ml/kg body weight/hour (corresponding to 0.21g glucose, 0.10g amino acids, and 0.08g lipids/kg bw/hour). The recommended infusion period is 14 - 24 hours. *Children (2-11 years)* – The infusion rate should not exceed 3.0ml/kg bw/hour (corresponding to 0.10g amino acids, 0.21g glucose and 0.08g lipids/kg bw/hour). The recommended infusion period is 12 – 24 hours. Recommended maximum daily dose is 40ml/kg bw/day. If using maximum daily dose, dose should be infused during a period of at least 13 hours. *Adolescents* – SmofKabiven Peripheral can be used as in adults. To provide total parenteral nutrition, trace elements, vitamins and possibly electrolytes should be added to SmofKabiven Peripheral according to the patient's need. **Contraindications:** Hypersensitivity to fish, egg, soya or peanut protein or to any of the active substances or excipients, severe hyperlipidaemia, severe liver insufficiency, severe blood coagulation disorders, congenital errors of amino acid metabolism, severe renal insufficiency without access to haemofiltration or dialysis, acute shock, uncontrolled hyperglycaemia, pathologically elevated serum levels of any of the included electrolytes, general contraindications to infusion therapy (acute pulmonary oedema, hyperhydration, decompensated cardiac insufficiency), haemophagocytotic syndrome, unstable conditions, infants and children under 2 years of age. **Special warnings and precautions for use (see SmPC for full details):** Use with caution in conditions of impaired lipid metabolism, in patients with a tendency towards electrolyte retention, in lactic acidosis, increased serum osmolarity and insufficient cellular oxygen supply. Contains soya-bean oil, fish oil and egg phospholipids which may rarely cause allergic reactions. Cross allergic reaction has been observed between soya-bean and peanut. Use a continuous and well-controlled infusion. Strict aseptic precautions should be taken. Electrolyte and fluid balance disturbances should be corrected prior to infusion. Special clinical monitoring is required at the beginning of any infusion and should any abnormal sign occur (including anaphylactic reaction), the infusion must be stopped. Carefully control phosphate and potassium intake in patients with renal insufficiency. Monitor triglyceride levels (serum concentration should not exceed 4mmol/l during infusion), serum glucose, electrolytes, osmolarity, fluid balance, acid-base status and liver enzyme tests. When lipids are given for a longer period, monitor blood cell count and coagulation. Lipid content may interfere with certain laboratory measurements if blood sampled before lipid clearance. Consider trace element dosing as intravenous infusion of amino acids is accompanied by increased urinary excretion of trace elements, in particular copper and zinc. Careful and slow initiation is recommended in malnourished patients with close monitoring and appropriate dose adjustments. Do not administer with blood in the same infusion set. Exogenous insulin may be necessary in patients with hyperglycaemia. No clinical experience in children (aged 2 to 16/18 years). Thrombophlebitis may occur if peripheral veins are used for infusions. **Undesirable effects:** Common – Thrombophlebitis, slight increase in body temperature. Uncommon – Lack of appetite, nausea, vomiting, elevated plasma levels of liver enzymes, chills, dizziness, headache. Rare – Tachycardia, dyspnoea, hypotension, hypertension, hypersensitivity reactions, heat or cold sensation, paleness, cyanosis, pain in the neck, back, bones, chest and loins. Other adverse reactions can occur (including fat overload syndrome), see SmPC for details. **Legal Category:** POM **Marketing Authorisation Number:** UK - PL 08828/0213, IE - PA 2059/061/002 **Marketing Authorisation Holder:** UK - Fresenius Kabi Limited, Cestrian Court, Eastgate Way, Manor Park, Runcorn, Cheshire, WA7 1NT, UK. IE – Fresenius Kabi Deutschland GmbH, Else-Kroener Strasse 1, Bad Homburg v.d.H. 61352, Germany. **Package Size and Cost:** 1904ml bag £63.84. **Further information:** Available from Fresenius Kabi Limited, Cestrian Court, Eastgate Way, Manor Park, Runcorn, Cheshire, WA7 1NT. Tel +44 (0)1928 533 533. **Date of preparation:** February 2021, API/SK-Peripheral-01

Prescribing Information - SmofKabiven® Central emulsion for infusion.

Consult the Summary of Product Characteristics for full information. Additional information is available on request. **Active ingredients:** ***1970ml bag*** Amino acid solution with electrolytes 1000ml, Glucose 42% 595ml, Lipid emulsion 375ml - corresponding to: Soya-bean oil, refined 22.5g, Medium-chain triglycerides 22.5g, Olive oil, refined 18.8g, Fish oil, rich in omega-3-acids 11.3g, Glucose (monohydrate) 250g, Alanine 14.0g, Arginine 12.0g, Glycine 11.0g, Histidine 3.0g, Isoleucine 5.0g, Leucine 7.4g, Lysine (as acetate) 6.6g, Methionine 4.3g, Phenylalanine 5.1g, Proline 11.2g, Serine 6.5g, Taurine 1.0g, Threonine 4.4g, Tryptophan 2.0g, Tyrosine 0.40g, Valine 6.2g, Calcium chloride (as dihydrate) 0.56g, Sodium glycerophosphate (as hydrate) 4.2g, Magnesium sulphate (as heptahydrate) 1.2g, Potassium chloride 4.5g, Sodium acetate (as trihydrate) 3.4g, Zinc sulphate (as heptahydrate) 0.013g ***1477ml bag*** Amino acid solution with electrolytes 750ml, Glucose 42% 446ml, Lipid emulsion 281ml - corresponding to: Soya-bean oil, refined 16.9g, Medium-chain triglycerides 16.9g, Olive oil, refined 14.1g, Fish oil, rich in omega-3-acids 8.4g, Glucose (monohydrate) 187g, Alanine 10.5g, Arginine 9.0g, Glycine 8.2g, Histidine 2.2g, Isoleucine 3.8g, Leucine 5.6g, Lysine (as acetate) 5.0g, Methionine 3.2g, Phenylalanine 3.8g, Proline 8.4g, Serine 4.9g, Taurine 0.75g, Threonine 3.3g, Tryptophan 1.5g, Tyrosine 0.30g, Valine 4.6g, Calcium chloride (as dihydrate) 0.42g, Sodium glycerophosphate (as hydrate) 3.1g, Magnesium sulphate (as heptahydrate) 0.9g, Potassium chloride 3.4g, Sodium acetate (as trihydrate) 2.6g, Zinc sulphate (as heptahydrate) 0.0097g ***986ml bag*** Amino acid solution with electrolytes 500ml, Glucose 42% 298ml, Lipid emulsion 188ml - corresponding to: Soya-bean oil, refined 11.3g, Medium-chain triglycerides 11.3g, Olive oil, refined 9.4g, Fish oil, rich in omega-3-acids 5.6g, Glucose (monohydrate) 125g, Alanine 7.0g, Arginine 6.0g, Glycine 5.5g, Histidine 1.5g, Isoleucine 2.5g, Leucine 3.7g, Lysine (as acetate) 3.3g, Methionine 2.2g, Phenylalanine 2.6g, Proline 5.6g, Serine 3.2g, Taurine 0.50g, Threonine 2.2g, Tryptophan 1.0g, Tyrosine 0.20g, Valine 3.1g, Calcium chloride (as dihydrate) 0.28g, Sodium glycerophosphate (as hydrate) 2.1g, Magnesium sulphate (as heptahydrate) 0.60g, Potassium chloride 2.2g, Sodium acetate (as trihydrate) 1.7g, Zinc sulphate (as heptahydrate) 0.0065g ***493ml bag*** Amino acid solution with electrolytes 250ml, Glucose 42% 149ml, Lipid emulsion 94ml – corresponding to: Soya-bean oil, refined 5.6g, Medium-chain triglycerides 5.6g, Olive oil, refined 4.7g, Fish oil, rich in omega-3-acids 2.8g, Glucose (monohydrate) 63g, Alanine 3.5g, Arginine 3.0g, Glycine 2.8g, Histidine 0.8g, Isoleucine 1.3g, Leucine 1.9g, Lysine (as acetate) 1.7g, Methionine 1.1g, Phenylalanine 1.3g, Proline 2.8g, Serine 1.6g, Taurine 0.25g, Threonine 1.1g, Tryptophan 0.5g, Tyrosine 0.10g, Valine 1.6g, Calcium chloride (as dihydrate) 0.14g, Sodium glycerophosphate (as hydrate) 1.1g, Magnesium sulphate (as heptahydrate) 0.30g, Potassium chloride 1.1g, Sodium acetate (as trihydrate) 0.9g, Zinc sulphate (as heptahydrate) 0.0033g**. Indications:** Parenteral nutrition for adults and children aged 2 years and above when oral or enteral nutrition is impossible, insufficient or contraindicated. **Dosage and administration:** Intravenous infusion into a central vein. The dose should be individualised to the patient's clinical condition, body weight (bw) and nutritional requirements. *Adults* - The dose range of 13-31 ml/kg bw/day covers the needs of the majority of patients. In obese patients the dose should be based on the estimated ideal weight. The recommended maximum daily dose is 35ml/kg bw/day. Infusion rate should not exceed 2.0ml/kg bw/hour (corresponding to 0.25g glucose, 0.10g amino acids, and 0.08g lipids /kg bw/hour). The recommended infusion period for adults is 14-24 hours. *Children (2-11 years)* - The infusion rate should not exceed 2.4ml/kg bw/hour (corresponding to 0.30g glucose, 0.12g amino acids and 0.09g lipids /kg bw/hour). At the maximum infusion rate, do not use an infusion period of longer than 14 hours and 30 minutes. The recommended infusion period in children aged 2-11 is 12-24 hours. The recommended maximum daily dose is 35ml/kg bw/day. *Adolescents* - SmofKabiven Central can be used as in adults. To provide total parenteral nutrition, trace elements, vitamins and possibly electrolytes should be added according to the patient's need. **Contraindications:** Hypersensitivity to fish-, egg-, soya- or peanut protein or to any of the active substances or excipients, severe hyperlipidaemia, severe liver insufficiency, severe blood coagulation disorders, congenital errors of amino acid metabolism, severe renal insufficiency without access to hemofiltration or dialysis, acute shock, uncontrolled hyperglycaemia, pathologically elevated serum levels of any of the included electrolytes, general contraindications to infusion therapy (acute pulmonary oedema, hyperhydration, decompensated cardiac insufficiency), hemophagocytotic syndrome, unstable conditions, infants and children under 2 years of age. **Special warnings and precautions for use:** See SmPC for further information. Use with caution in conditions of impaired lipid metabolism, in patients with a tendency towards electrolyte retention, in lactic acidosis, increased serum osmolarity and insufficient cellular oxygen supply. Contains soya-bean oil, fish oil and egg phospholipids which may rarely cause allergic reactions. Cross allergic reaction has been observed between soya-bean and peanut. Use a continuous and well-controlled infusion. Strict aseptic precautions should be taken. Electrolyte and fluid balance disturbances should be corrected prior to infusion. Special clinical monitoring is required at the beginning of any infusion and should any abnormal sign occur (including anaphylactic reaction), the infusion must be stopped. Carefully control phosphate and potassium intake in patients with renal insufficiency. Monitor triglyceride levels (serum concentration should not exceed 4mmol/l during infusion), serum glucose, electrolytes, osmolarity, fluid balance, acid-base status and liver enzyme tests. When lipids are given for a longer period, monitor blood cell count and coagulation. Lipid content may interfere with certain laboratory measurements if blood sampled before lipid clearance. Consider trace element dosing as intravenous infusion of amino acids is accompanied by increased urinary excretion of trace elements, in particular copper and zinc. Careful and slow initiation is recommended in malnourished patients with close monitoring and appropriate dose adjustments. Do not administer with blood in the same infusion set. Exogenous insulin may be necessary in patients with hyperglycaemia. No clinical experience in children (aged 2 to 16/18 years). **Undesirable effects:** Common – Slight increase in body temperature. Uncommon – Lack of appetite, nausea, vomiting, elevated plasma levels of liver enzymes, chills, dizziness, headache. Rare – Tachycardia, dyspnoea, hypotension, hypertension, hypersensitivity reactions, heat or cold sensation, paleness, cyanosis, pain in the neck, back, bones, chest and loins. Other adverse reactions can occur (including fat overload syndrome), see SmPC for details. **Legal Category:** POM **Marketing Authorisation Number:** UK - PL 08828/0187. IE – PA 2059/058/002 Biofine Bags. **Marketing Authorisation Holder:** UK - Fresenius Kabi Limited, Cestrian Court, Eastgate Way, Manor Park, Runcorn, Cheshire, WA7 1NT, UK. IE – Fresenius Kabi Deutschland GmbH, Else-Kroener Strasse 1, Bad Homburg v.d.h. 61352, Germany. **Package size and cost:** 1970ml £67.73, 1477ml £64.05, 986ml £63.58, 493ml £58.00. **Further information:** Available from Fresenius Kabi Limited, Cestrian Court, Eastgate Way, Manor Park, Runcorn, Cheshire, WA7 1NT. Tel +44 (0)1928 533 533. **Date of preparation:** October 2020 API/SMOFKabiven-02

Prescribing Information - SmofKabiven® Electrolyte Free Central emulsion for infusion.

Consult the Summary of Product Characteristics for full information. Additional information is available on request. **Active ingredients:** ***1970ml bag*** Amino acid solution 1000ml, Glucose 42% 595ml, Lipid emulsion 375ml - corresponding to: Soya-bean oil, refined 22.5g, Medium-chain triglycerides 22.5g, Olive oil, refined 18.8g, Fish oil, rich in omega-3-acids 11.3g, Glucose (monohydrate) 250g, Alanine 14.0g, Arginine 12.0g, Glycine 11.0g, Histidine 3.0g, Isoleucine 5.0g, Leucine 7.4g, Lysine (as acetate) 6.6g, Methionine 4.3g, Phenylalanine 5.1g, Proline 11.2g, Serine 6.5g, Taurine 1.0g, Threonine 4.4g, Tryptophan 2.0g, Tyrosine 0.40g, Valine 6.2g ***1477ml bag*** Amino acid solution 750ml, Glucose 42% 446ml, Lipid emulsion 281ml - corresponding to: Soya-bean oil, refined 16.9g, Medium-chain triglycerides 16.9g, Olive oil, refined 14.1g, Fish oil, rich in omega-3-acids 8.4g, Glucose (monohydrate) 187g, Alanine 10.5g, Arginine 9.0g, Glycine 8.2g, Histidine 2.2g, Isoleucine 3.8g, Leucine 5.6g, Lysine (as acetate) 5.0g, Methionine 3.2g, Phenylalanine 3.8g, Proline 8.4g, Serine 4.9g, Taurine 0.75g, Threonine 3.3g, Tryptophan 1.5g, Tyrosine 0.30g, Valine 4.6g ***986ml bag*** Amino acid solution 500ml, Glucose 42% 298ml, Lipid emulsion 188ml - corresponding to: Soya-bean oil, refined 11.3g, Medium-chain triglycerides 11.3g, Olive oil, refined 9.4g, Fish oil, rich in omega-3-acids 5.6g, Glucose (monohydrate) 125g, Alanine 7.0g, Arginine 6.0g, Glycine 5.5g, Histidine 1.5g, Isoleucine 2.5g, Leucine 3.7g, Lysine (as acetate) 3.3g, Methionine 2.2g, Phenylalanine 2.6g, Proline 5.6g, Serine 3.2g, Taurine 0.50g, Threonine 2.2g, Tryptophan 1.0g, Tyrosine 0.20g, Valine 3.1g **Indications:** Parenteral nutrition for adults and children aged 2 years and above when oral or enteral nutrition is impossible, insufficient or contraindicated. **Dosage and administration:** Intravenous infusion into a central vein. The dose should be individualised to the patient's clinical condition, body weight (bw) and nutritional requirements. *Adults* - The dose range of 13-31 ml/kg bw/day covers the needs of the majority of patients. In obese patients the dose should be based on the estimated ideal weight. The recommended maximum daily dose is 35ml/kg bw/day. Infusion rate should not exceed 2.0ml/kg bw/hour (corresponding to 0.25g glucose, 0.10g amino acids, and 0.08g lipids /kg bw/hour). The recommended infusion period for adults is 14-24 hours. *Children (2-11 years)* - The infusion rate should not exceed 2.4ml/kg bw/hour (corresponding to 0.30g glucose, 0.12g amino acids and 0.09g lipids /kg bw/hour). At the maximum infusion rate, do not use an infusion period of longer than 14 hours and 30 minutes. The recommended infusion period in children aged 2-11 is 12-24 hours. The recommended maximum daily dose is 35ml/kg bw/day. *Adolescents* - Use as in adults. To provide total parenteral nutrition, trace elements, vitamins and electrolytes should be added according to the patient's need. **Contraindications:** Hypersensitivity to fish-, egg-, soya- or peanut protein or to any of the active substances or excipients, severe hyperlipidaemia, severe liver insufficiency, severe blood coagulation disorders, congenital errors of amino acid metabolism, severe renal insufficiency without access to hemofiltration or dialysis, acute shock, uncontrolled hyperglycaemia, general contraindications to infusion therapy (acute pulmonary oedema, hyperhydration, decompensated cardiac insufficiency), hemophagocytotic syndrome, unstable conditions, infants and children under 2 years of age. **Special warnings and precautions for use:** See SmPC for further information. Use with caution in conditions of impaired lipid metabolism, in lactic acidosis, increased serum osmolarity and insufficient cellular oxygen supply. Contains soya-bean oil, fish oil and egg phospholipids which may rarely cause allergic reactions. Cross allergic reaction has been observed between soya-bean and peanut. Use a continuous and well-controlled infusion. Strict aseptic precautions should be taken. Special clinical monitoring is required at the beginning of any infusion and should any abnormal sign occur (including anaphylactic reaction), the infusion must be stopped. Carefully control phosphate intake in patients with renal insufficiency. Monitor triglyceride levels (serum concentration should not exceed 4mmol/l during infusion), serum glucose, electrolytes, osmolarity, fluid balance, acid-base status and liver enzyme tests. Electrolytes should be added governed by clinical condition of patient and by frequent monitoring of serum levels. When lipids are given for a longer period, monitor blood cell count and coagulation. Lipid content may interfere with certain laboratory measurements if blood sampled before lipid clearance. Consider trace element dosing as intravenous infusion of amino acids is accompanied by increased urinary excretion of trace elements, in particular copper and zinc. Careful and slow initiation is recommended in malnourished patients with close monitoring and appropriate dose adjustments. Do not administer with blood in the same infusion set. Exogenous insulin may be necessary in patients with hyperglycaemia. No clinical experience in children (aged 2 to 16/18 years). **Undesirable effects:** Common – Slight increase in body temperature. Uncommon – Lack of appetite, nausea, vomiting, elevated plasma levels of liver enzymes, chills, dizziness, headache. Rare – Tachycardia, dyspnoea, hypotension, hypertension, hypersensitivity reactions, heat or cold sensation, paleness, cyanosis, pain in the neck, back, bones, chest and loins. Other adverse reactions can occur (including fat overload syndrome), see SmPC for details. **Legal Category:** POM **Marketing Authorisation Number:** UK - PL 08828/0188 IE - PPA 2059/059/002, PA 2059/059/001 **Marketing Authorisation Holder:** UK - Fresenius Kabi Limited, Cestrian Court, Eastgate Way, Manor Park, Runcorn, Cheshire, WA7 1NT, UK. IE – Fresenius Kabi Deutschland GmbH, Else-Kroener Strasse 1, Bad Homburg v.d.h. 61352, Germany. **Package size and cost:** 1970ml £67.73, 1477ml £64.05, 986ml £63.58 **Further information:** Available from Fresenius Kabi Limited, Cestrian Court, Eastgate Way, Manor Park, Runcorn, Cheshire, WA7 1NT. Tel +44 (0)1928 533 533. **Date of preparation:** February 2021 API/SK-EFCentral-01

Prescribing Information - SmofKabiven® extra Nitrogen, emulsion for infusion.

Consult the Summary of Product Characteristics for full information. Additional information is available on request. **Active Ingredients:** ***2025ml bag*** Amino acid solution 10% with electrolytes 1325ml, Glucose 42% 408ml, Lipid emulsion 20% 292ml – corresponding to: Soya-bean oil (refined) 18g, Medium-chain triglycerides 18g, Olive oil (refined) 15g, Fish oil (rich in omega-3-acids) 8.8g, Glucose (monohydrate) 171g, Alanine 19g, Arginine 16g, Glycine 15g, Histidine 4.0g, Isoleucine 6.6g, Leucine 9.8g, Lysine (as acetate) 8.7g, Methionine 5.7g, Phenylalanine 6.8g, Proline 15g, Serine 8.6g, Taurine 1.3g, Threonine 5.8g, Tryptophan 2.7g, Tyrosine 0.53g, Valine 8.2g, Calcium chloride (as dihydrate) 0.58g, Sodium glycerophosphate (as hydrate) 4.6g, Magnesium sulphate (as heptahydrate) 1.2g, Potassium chloride 4.6g, Sodium acetate (as trihydrate) 3.3g, Zinc sulphate (as heptahydrate) 0.013g ***1518ml bag*** Amino acid solution 10% with electrolytes 993ml, Glucose 42% 306ml, Lipid emulsion 20% 219ml – corresponding to: Soya-bean oil (refined) 13g, Medium-chain triglycerides 13g, Olive oil (refined) 11g, Fish oil (rich in omega-3-acids) 6.6g, Glucose (monohydrate) 129g, Alanine 14g, Arginine 12g, Glycine 11g, Histidine 3.0g, Isoleucine 5.0g, Leucine 7.3g, Lysine (as acetate) 6.6g, Methionine 4.3g, Phenylalanine 5.1g, Proline 11g, Serine 6.5g, Taurine 1.0g, Threonine 4.4g, Tryptophan 2.0g, Tyrosine 0.40g, Valine 6.2g, Calcium chloride (as dihydrate) 0.43g, Sodium glycerophosphate (as hydrate) 3.5g, Magnesium sulphate (as heptahydrate) 0.92g, Potassium chloride 3.5g, Sodium acetate (as trihydrate) 2.5g, Zinc sulphate (as heptahydrate) 0.010g ***1012ml bag*** Amino acid solution 10% with electrolytes 662ml, Glucose 42% 204ml, Lipid emulsion 20% 146ml – corresponding to: Soya-bean oil (refined) 8.8g, Medium-chain triglycerides 8.8g, Olive oil (refined) 7.3g, Fish oil (rich in omega-3-acids) 4.4g, Glucose (monohydrate) 86g, Alanine 9.3g, Arginine 7.9g, Glycine 7.3g, Histidine 2.0g, Isoleucine 3.3g, Leucine 4.9g, Lysine (as acetate) 4.4g, Methionine 2.8g, Phenylalanine 3.4g, Proline 7.4g, Serine 4.3g, Taurine 0.66g, Threonine 2.9g, Tryptophan 1.3g, Tyrosine 0.26g, Valine 4.1g, Calcium chloride (as dihydrate) 0.29g, Sodium glycerophosphate (as hydrate) 2.3g, Magnesium sulphate (as heptahydrate) 0.62g, Potassium chloride 2.3g, Sodium acetate (as trihydrate) 1.6g, Zinc sulphate (as heptahydrate) 0.0066g **Indications:** Parenteral nutrition for adults and children aged 2 years and above when oral or enteral nutrition is impossible, insufficient or contraindicated. **Dosage and administration:** Intravenous infusion into a central vein. The dose should be individualised to the patient's clinical condition, body weight (bw) and nutritional requirements. *Adults* – Dosage range of 13-31ml/kg bw/day covers the needs of the majority of patients. In obese patients dose should be based on estimated ideal weight. The recommended maximum daily dose is 31ml/kg bw/day. Adult infusion rate should not exceed 1.5ml/kg bw/hour (corresponding to 0.13g glucose, 0.10g amino acids, and 0.04g lipids/kg bw/hour). The recommended infusion period is 14-24 hours. *Children (2-11 years)* - the recommended maximum infusion rate is 1.8ml/kg bw/hour (corresponding to 0.15g glucose, 0.12g amino acids, and 0.05g lipids/kg/hour). Maximum daily dose is 31ml/kg bw/day. The recommended infusion period is 12-24 hours. At the maximum infusion rate, do not use an infusion period longer than 17 hours, except in exceptional cases and with careful monitoring. *Adolescents (12-16/18 years)* - Use as in adults. To provide total parenteral nutrition, trace elements, vitamins and possibly electrolytes should be added according to the patient's need (check compatibility). **Contraindications:** Hypersensitivity to fish-, egg, soya- or peanut protein or to any of the active substances or excipients, severe hyperlipidaemia, severe liver insufficiency, severe blood coagulation disorders, congenital errors of amino acid metabolism, severe renal insufficiency without access to hemofiltration or dialysis, acute shock, uncontrolled hyperglycaemia, pathologically elevated serum levels of any of the included electrolytes, general contraindications to infusion therapy: acute pulmonary oedema, hyperhydration, decompensated cardiac insufficiency; hemophagocytotic syndrome, unstable conditions, neonates and infants under 2 years of age. **Special warnings and precautions for use:** The patient's ability to eliminate lipid should be monitored by checking triglyceride levels. Serum triglyceride concentration should not exceed 4 mmol/l during infusion. Disturbances of electrolyte and fluid balance should be corrected before starting the infusion. Special clinical monitoring is required at the beginning of any intravenous infusion and should any abnormal sign occur, the infusion must be stopped. Strict aseptic precautions should be taken. Use a continuous and well controlled infusion. Use with caution in conditions of impaired lipid metabolism. Monitor serum glucose, electrolytes, osmolarity, fluid balance, acid-base status, liver enzyme tests. Blood cell count and coagulation should be monitored when lipids are given for a longer period. Use with caution in lactic acidosis, insufficient cellular oxygen supply, increased serum osmolarity, in patients with a tendency to electrolyte retention, in malnourished patients (careful and slow initiation recommended with close monitoring and appropriate dose adjustments) and patients with renal insufficiency (carefully control phosphate and potassium intake). Any sign or symptom of anaphylactic reaction (such as fever, shivering, rash or dyspnoea) should lead to the immediate interruption of the infusion. Contains soya-bean oil, fish oil and egg phospholipids, which may rarely cause allergic reactions. Cross allergic reaction has been observed between soya-bean and peanut. Electrolyte additions should be governed by patient's clinical condition and frequent monitoring. Consider trace element dosing, especially during long-term administration. Lipid content may interfere with laboratory measurements if blood sampled before lipid is cleared from bloodstream. Do not administer with blood in the same infusion set. Exogenous insulin may be necessary in patients with hyperglycaemia. Not suitable for use in newborns or infants below 2 years of age. No clinical experience in children and adolescents age 2 years to 16/18 years. **Undesirable effects:** *Common* - slight increase in body temperature. *Uncommon* - nausea, vomiting, lack of appetite, headache, elevated plasma levels of liver enzymes, chills, dizziness. *Rare* – tachycardia, dyspnoea, hypotension, hypertension, hypersensitivity reactions, heat or cold sensation, paleness, cyanosis, pain in the neck, back, bones, chest and loins. Other adverse reactions can occur (including fat overload syndrome) see SmPC for details. **Legal Category:** POM. **Marketing Authorisation Number:** UK: PL 08828/0268, IE: PA 2059/060/001. **Marketing Authorisation Holder:** UK: Fresenius Kabi Limited, Cestrian Court, Eastgate Way, Manor Park, Runcorn, Cheshire, WA7 1NT, UK. IE: Fresenius Kabi Deutschland GmbH, Else-Kroener Strasse 1, Bad Homburg v.d.H. 61352, Germany. **Package Size and Cost:** 2025ml £89.00, 1518ml £80.00, 1012ml £75.00. **Further information:** Available from Fresenius Kabi Limited, Cestrian Court, Eastgate Way, Manor Park, Runcorn, Cheshire, WA7 1NT. Tel +44 (0)1928 533 533. **Date of preparation:** February 2021 API/SKEN-01

Prescribing Information - SmofKabiven® extra Nitrogen Electrolyte free, emulsion for infusion.

Consult the Summary of Product Characteristics for full information. Additional information is available on request. **Active Ingredients:** ***2025ml bag*** Amino acid solution 10% 1325ml, Glucose 42% 408ml, Lipid emulsion 20% 292ml – corresponding to: Soya-bean oil (refined) 18g, Medium-chain triglycerides 18g, Olive oil (refined) 15g, Fish oil (rich in omega-3-acids) 8.8g, Glucose (monohydrate) 171g, Alanine 19g, Arginine 16g, Glycine 15g, Histidine 4.0g, Isoleucine 6.6g, Leucine 9.8g, Lysine (as acetate) 8.7g, Methionine 5.7g, Phenylalanine 6.8g, Proline 15g, Serine 8.6g, Taurine 1.3g, Threonine 5.8g, Tryptophan 2.7g, Tyrosine 0.53g, Valine 8.2g ***1518ml bag*** Amino acid solution 10% 993ml, Glucose 42% 306ml, Lipid emulsion 20% 219ml – corresponding to: Soya-bean oil (refined) 13g, Medium-chain triglycerides 13g, Olive oil (refined) 11g, Fish oil (rich in omega-3-acids) 6.6g, Glucose (monohydrate) 129g, Alanine 14g, Arginine 12g, Glycine 11g, Histidine 3.0g, Isoleucine 5.0g, Leucine 7.3g, Lysine (as acetate) 6.6g, Methionine 4.3g, Phenylalanine 5.1g, Proline 11g, Serine 6.5g, Taurine 1.0g, Threonine 4.4g, Tryptophan 2.0g, Tyrosine 0.40g, Valine 6.2g ***1012ml bag*** Amino acid solution 10% 662ml, Glucose 42% 204ml, Lipid emulsion 20% 146ml – corresponding to: Soya-bean oil (refined) 8.8g, Medium-chain triglycerides 8.8g, Olive oil (refined) 7.3g, Fish oil (rich in omega-3-acids) 4.4g, Glucose (monohydrate) 86g, Alanine 9.3g, Arginine 7.9g, Glycine 7.3g, Histidine 2.0g, Isoleucine 3.3g, Leucine 4.9g, Lysine (as acetate) 4.4g, Methionine 2.8g, Phenylalanine 3.4g, Proline 7.4g, Serine 4.3g, Taurine 0.66g, Threonine 2.9g, Tryptophan 1.3g, Tyrosine 0.26g, Valine 4.1g **Indications:** Parenteral nutrition for adults and children aged 2 years and above when oral or enteral nutrition is impossible, insufficient or contraindicated. **Dosage and administration:** Intravenous infusion into a central vein. The dose should be individualised to the patient's clinical condition, body weight (bw) and nutritional requirements. *Adults* – Dosage range of 13-31ml/kg bw/day covers the needs of the majority of patients. In obese patients dose should be based on estimated ideal weight. The recommended maximum daily dose is 31ml/kg bw/day. Adult infusion rate should not exceed 1.5ml/kg bw/hour (corresponding to 0.13g glucose, 0.10g amino acids, and 0.04g lipids/kg bw/hour). The recommended infusion period is 14-24 hours. *Children (2-11 years)* - the recommended maximum infusion rate is 1.8ml/kg bw/hour (corresponding to 0.15g glucose, 0.12g amino acids, and 0.05g lipids/kg/hour). Maximum daily dose is 31ml/kg bw/day. The recommended infusion period is 12-24 hours. At the maximum infusion rate, do not use an infusion period longer than 17 hours, except in exceptional cases and with careful monitoring. *Adolescents (12-16/18 years)* – Use as in adults. To provide total parenteral nutrition, trace elements, vitamins and electrolytes should be added according to the patient's need (check compatibility). **Contraindications:** Hypersensitivity to fish-, egg-, soya- or peanut protein or to any of the active substances or excipients, severe hyperlipidaemia, severe liver insufficiency, severe blood coagulation disorders, congenital errors of amino acid metabolism, severe renal insufficiency without access to hemofiltration or dialysis, acute shock, uncontrolled hyperglycaemia, general contraindications to infusion therapy: acute pulmonary oedema, hyperhydration, decompensated cardiac insufficiency; hemophagocytotic syndrome, unstable conditions, neonates and infants under 2 years of age. **Special warnings and precautions for use:** The patient's ability to eliminate lipid should be monitored by checking triglyceride levels. Serum triglyceride concentration should not exceed 4 mmol/l during infusion. Strict aseptic precautions should be taken. Use a continuous and well controlled infusion. Use with caution in conditions of impaired lipid metabolism. Monitor serum glucose, electrolytes, osmolarity, fluid balance, acid-base status, liver enzyme tests. Blood cell count and coagulation should be monitored when lipids are given for a longer period. Use with caution in lactic acidosis, insufficient cellular oxygen supply, increased serum osmolarity, in malnourished patients (careful and slow initiation recommended with close monitoring and appropriate dose adjustments) and patients with renal insufficiency (carefully control phosphate and potassium intake). Any sign or symptom of anaphylactic reaction (such as fever, shivering, rash or dyspnoea) should lead to the immediate interruption of the infusion. Contains soya-bean oil, fish oil and egg phospholipids, which may rarely cause allergic reactions. Cross allergic reaction has been observed between soya-bean and peanut. Electrolyte additions should be governed by patient's clinical condition and frequent monitoring. Consider trace element dosing, especially during long-term administration. Lipid content may interfere with laboratory measurements if blood sampled before lipid is cleared from bloodstream. Do not administer with blood in the same infusion set. Exogenous insulin may be necessary in patients with hyperglycaemia. Not suitable for use in newborns or infants below 2 years of age. No clinical experience in children and adolescents age 2 years to 16/18 years. **Undesirable effects:** *Common* - slight increase in body temperature. *Uncommon* - nausea, vomiting, lack of appetite, headache, elevated plasma levels of liver enzymes, chills, dizziness. *Rare* – tachycardia, dyspnoea, hypotension, hypertension, hypersensitivity reactions, heat or cold sensation, paleness, cyanosis, pain in the neck, back, bones, chest and loins. Other adverse reactions can occur (including fat overload syndrome), see SmPC for details. **Legal Category:** POM. **Marketing Authorisation Number:** UK: PL 08828/0269, IE: PA 2059/060/002. **Marketing Authorisation Holder:** UK: Fresenius Kabi Limited, Cestrian Court, Eastgate Way, Manor Park, Runcorn, Cheshire, WA7 1NT, UK. IE: Fresenius Kabi Deutschland GmbH, Else-Kroener Strasse 1, Bad Homburg v.d.H. 61352, Germany. **Package Size and Cost:** 2025ml £89.00, 1518ml £80.00, 1012ml £75.00. **Further information:** Available from Fresenius Kabi Limited, Cestrian Court, Eastgate Way, Manor Park, Runcorn, Cheshire, WA7 1NT. Tel +44 (0)1928 533 533. **Date of preparation:** February 2021 API/SKEN-EF-01

Prescribing Information - SmofKabiven® Low Osmo Peripheral emulsion for infusion.

Consult the Summary of Product Characteristics for full information. Additional information is available on request. **Active Ingredients: 2500ml bag** Amino acid solution 10% with electrolytes 625ml, Glucose 11.8% 1438ml, Lipid emulsion 20% 438ml – corresponding to: Soya-bean oil (refined) 26g, Medium-chain triglycerides 26g, Olive oil (refined) 22g, Fish oil (rich in omega-3-acids) 13g, Glucose (as monohydrate) 170g, Alanine 8.8g, Arginine 7.5g, Glycine 6.9g, Histidine 1.9g, Isoleucine 3.1g, Leucine 4.6g, Lysine (as acetate) 4.1g, Methionine 2.7g, Phenylalanine 3.2g, Proline 7.0g, Serine 4.1g, Taurine 0.63g, Threonine 2.8g, Tryptophan 1.3g, Tyrosine 0.25g, Valine 3.9g, Calcium chloride (as dihydrate) 0.35g, Sodium glycerophosphate (as hydrate) 2.6g, Magnesium sulphate (as heptahydrate) 0.75g, Potassium chloride 2.8g, Sodium acetate (as trihydrate) 2.1g, Zinc sulphate (as heptahydrate) 0.0081g **1950ml bag** Amino acid solution 10% with electrolytes 488ml, Glucose 11.8% 1121ml, Lipid emulsion 20% 341ml – corresponding to: Soya-bean oil (refined) 20g, Medium-chain triglycerides 20g, Olive oil (refined) 17g, Fish oil (rich in omega-3-acids) 10g, Glucose (as monohydrate) 130g, Alanine 6.8g, Arginine 5.9g, Glycine 5.4g, Histidine 1.5g, Isoleucine 2.4g, Leucine 3.6g, Lysine (as acetate) 3.2g, Methionine 2.1g, Phenylalanine 2.5g, Proline 5.5g, Serine 3.2g, Taurine 0.49g, Threonine 2.1g, Tryptophan 0.98g, Tyrosine 0.20g, Valine 3.0g, Calcium chloride (as dihydrate) 0.27g, Sodium glycerophosphate (as hydrate) 2.0g, Magnesium sulphate (as heptahydrate) 0.59g, Potassium chloride 2.2g, Sodium acetate (as trihydrate) 1.7g, Zinc sulphate (as heptahydrate) 0.0063g **1400ml bag** Amino acid solution 10% with electrolytes 350ml, Glucose 11.8% 805ml, Lipid emulsion 20% 245ml – corresponding to: Soya-bean oil (refined) 15g, Medium-chain triglycerides 15g, Olive oil (refined) 12g, Fish oil (rich in omega-3-acids) 7.4g, Glucose (as monohydrate) 95g, Alanine 4.9g, Arginine 4.2g, Glycine 3.9g, Histidine 1.1g, Isoleucine 1.8g, Leucine 2.6g, Lysine (as acetate) 2.3g, Methionine 1.5g, Phenylalanine 1.8g, Proline 3.9g, Serine 2.3g, Taurine 0.35g, Threonine 1.5g, Tryptophan 0.7g, Tyrosine 0.14g, Valine 2.2g, Calcium chloride (as dihydrate) 0.20g, Sodium glycerophosphate (as hydrate) 1.5g, Magnesium sulphate (as heptahydrate) 0.42g, Potassium chloride 1.6g, Sodium acetate (as trihydrate)1.2g, Zinc sulphate (as heptahydrate) 0.0045g **Indications:** Parenteral nutrition for adults and children aged 2 years and above when oral or enteral nutrition is impossible, insufficient or contraindicated. **Dosage and administration:** Intravenous infusion into a central or peripheral vein. The dose should be individualised to the patient's clinical condition, body weight (bw), nutritional and energy requirements. *Adults* - The dose range of 20-40 ml/kg bw/day covers the needs of the majority of patients. In obese patients the dose should be based on the estimated ideal weight. The recommended maximum daily dose is 40 ml/kg bw/day. Infusion rate should not exceed 3.7 ml/kg bw/hour (corresponding to 0.25 g glucose, 0.09 g amino acids, and 0.13 g lipids/kg bw/hour). The recommended infusion period for adults is 12-24 hours. *Children (2-11 years)* - The infusion rate should not exceed 4.0 ml/kg bw/hour (corresponding to 0.27 g glucose, 0.10 g amino acids and 0.14 g lipids/kg/hour). At the maximum infusion rate, do not use an infusion period of longer than 10 hours, except in exceptional circumstances with careful monitoring. The recommended infusion period in children aged 2-11 is 12-24 hours. The recommended maximum daily dose is 40 ml/kg bw/day. *Adolescents* - SmofKabiven Low Osmo Peripheral can be used as in adults. To provide total parenteral nutrition, trace elements, vitamins and possibly electrolytes should be added according to the patient's need. **Contraindications:** Hypersensitivity to fish-, egg-, soya- or peanut protein or to any of the active substances or excipients, severe hyperlipidaemia, severe liver insufficiency, severe blood coagulation disorders, congenital errors of amino acid metabolism, severe renal insufficiency without access to haemofiltration or dialysis, acute shock, uncontrolled hyperglycaemia, pathologically elevated serum levels of any of the included electrolytes, general contraindications to infusion therapy (acute pulmonary oedema, hyperhydration, decompensated cardiac insufficiency), haemophagocytotic syndrome, unstable conditions, neonates and infants under 2 years of age. **Special warnings and precautions for use:** See SmPC for further information. Use with caution in conditions of impaired lipid metabolism, in patients with a tendency towards electrolyte retention, in lactic acidosis, increased serum osmolarity and insufficient cellular oxygen supply. Contains soya-bean oil, fish oil and egg phospholipids which may rarely cause allergic reactions. Cross allergic reaction has been observed between soya-bean and peanut. Use a continuous and well-controlled infusion. Strict aseptic precautions should be taken. Electrolyte and fluid balance disturbances should be corrected prior to infusion. Special clinical monitoring is required at the beginning of any infusion and should any abnormal sign occur (including anaphylactic reaction), the infusion must be stopped. Carefully control phosphate and potassium intake in patients with renal insufficiency. Monitor triglyceride levels (serum concentration should not exceed 4 mmol/l during infusion), serum glucose, electrolytes, osmolarity, fluid balance, acid-base status and liver enzyme tests. When lipids are given for a longer period, monitor blood cell count and coagulation. Lipid content may interfere with certain laboratory measurements if blood sampled before lipid clearance. Consider trace element dosing as intravenous infusion of amino acids is accompanied by increased urinary excretion of trace elements, in particular copper and zinc. Careful and slow initiation is recommended in malnourished patients with close monitoring and appropriate dose adjustments. Do not administer with blood in the same infusion set. Exogenous insulin may be necessary in patients with hyperglycaemia. Thrombophlebitis may occur if peripheral veins used for infusion. No clinical experience in children (aged 2 to 16/18 years). **Undesirable effects:** Common – Slight increase in body temperature, within a few days vein irritation, phlebitis or thrombophlebitis. Uncommon – Lack of appetite, nausea, vomiting, elevated plasma levels of liver enzymes, chills, dizziness, headache. Rare – Tachycardia, dyspnoea, hypotension, hypertension, hypersensitivity reactions, heat or cold sensation, paleness, cyanosis, pain in the neck, back, bones, chest and loins. Other adverse reactions can occur (including fat overload syndrome), see SmPC for details. **Legal Category:** POM **Marketing Authorisation Number:** UK: PL 08828/0274. IE: PA 2059/022/001. **Marketing Authorisation Holder**: UK - Fresenius Kabi Limited, Cestrian Court, Eastgate Way, Manor Park, Runcorn, Cheshire WA7 1NT, UK. IE – Fresenius Kabi Deutschland GmbH, Else-Kroener Strasse 1, Bad Homburg v.d.h. 61352, Germany. **Package Size and Cost:** 2500ml £68.00, 1950ml £61.00, 1400ml £58.00. **Further information:** Available from Fresenius Kabi Limited, Cestrian Court, Eastgate Way, Manor Park, Runcorn, Cheshire, WA7 1NT. Tel +44 (0)1928 533 533. **Date of preparation:** October 2020 API/LowOsmo-01

Prescribing information – Kabiven® Peripheral emulsion for infusion.

Consult the Summary of Product Characteristics for full information. Additional Information is available on request. **Kabiven® Peripheral emulsion for infusion. Active Ingredients:** *2400ml bag* Glucose 11% 1475ml, Amino acids and electrolytes (Vamin® 18 Novum) 500ml, Fat emulsion (Intralipid 20%) 425ml - corresponding to: Purified soybean oil 85g, Glucose (as anyhdrous) 162g, Alanine 8g, Arginine 5.6g, Aspartic acid 1.7g, Glutamic acid 2.8g, Glycine 4g, Histidine 3.4g, Isoleucine 2.8g, Leucine 4g, Lysine 4.5g, Methionine 2.8g, Phenylalanine 4g, Proline 3.4g, Serine 2.2g, Threonine 2.8g, Tryptophan 0.95g, Tyrosine 0.12g, Valine 3.6g, Calcium chloride 0.37g, Sodium glycerophosphate 2.5g, Magnesium sulphate 0.8g, Potassium chloride 3g, Sodium acetate 2.4g. *1920ml bag* Glucose 11% 1180ml, Amino acids and electrolytes (Vamin® 18 Novum) 400ml, Fat emulsion (Intralipid 20%) 340ml - corresponding to: Purified soybean oil 68g, Glucose (as anhydrous) 130g, Alanine 6.4g, Arginine 4.5g, Aspartic acid 1.4g, Glutamic acid 2.2g, Glycine 3.2g, Histidine 2.7g, Isoleucine 2.2g, Leucine 3.2g, Lysine 3.6g, Methionine 2.2g, Phenylalanine 3.2g, Proline 2.7g, Serine 1.8g, Threonine 2.2g, Tryptophan 0.76g, Tyrosine 0.092g, Valine 2.9g, Calcium chloride 0.3g, Sodium glycerophosphate 2g, Magnesium sulphate 0.64g, Potassium chloride 2.4g, Sodium acetate 2g. *1440ml bag* Glucose 11% 885ml, Amino acids and electrolytes (Vamin®18 Novum) 300ml, Fat emulsion (Intralipid 20%) 255ml – corresponding to: Purified soybean oil 51g, Glucose (as anhydrous) 97g, Alanine 4.8g, Arginine 3.4g, Aspartic acid 1g, Glutamic acid 1.7g, Glycine 2.4g, Histidine 2g, Isoleucine 1.7g, Leucine 2.4g, Lysine 2.7g, Methionine 1.7g, Phenylalanine 2.4g, Proline 2g, Serine 1.4g , Threonine 1.7g, Tryptophan 0.57g, Tyrosine 0.069g, Valine 2.2g, Calcium chloride 0.22g, Sodium glycerophosphate 1.5g, Magnesium sulphate 0.48g, Potassium chloride 1.8g, Sodium acetate 1.5g. **Indications:** Parenteral nutrition for patients and children above 2 years of age when oral or enteral nutrition is impossible, insufficient or contraindicated. **Dosage and Administration:** The dose should be individualised and the choice of bag size should be made with regard to the patient's clinical condition, body weight (bw) and nutritional requirements. Intravenous infusion into a peripheral or central vein. Infusion may be continued for as long as required by the patient's clinical condition. In order to minimize the risk of thrombophlebitis for peripheral application, daily rotation of infusion site is recommended. *Adults:* the nitrogen requirements for maintenance of body protein mass depend on the patient's condition (e.g. nutritional state and degree of catabolic stress). The dose range of 0.10-0.15 g nitrogen/kg bw/day and a total energy of 20-30kcal bw/day corresponds to approximately 27-40ml/kg bw/day. In obese patients doses should be based on estimated ideal weight. To provide total parenteral nutrition, trace elements and vitamins may be required. *Children:* the ability to metabolise individual nutrients must determine the dosage. In general the infusion for small children (2-10 years) should start with a low dose i.e. 14-28ml/kg and increased by 10-15ml/kg/day up to maximum dosage of 40ml/kg/day. For children over 10 years of age the dosage for adults can be applied. The use of Kabiven® Peripheral is not recommended in children under 2 years of age. The infusion rate should not exceed 3.7ml/kg bw/hour (corresponding to 0.25g glucose, 0.09g amino acids and 0.13g fat/kg bw). The recommended infusion period for individual Kabiven® Peripheral bags is 12-24 hours. Maximum daily dose 40ml/kg bw/day. The maximum daily dose varies with the clinical condition of the patient and may even change from day to day. **Contraindications:** Hypersensitivity to egg, soya or peanut protein or to any of the active substances or excipients. Severe hyperlipaemia, severe liver insufficiency, severe blood coagulation disorders, inborn errors of amino acid metabolism, severe renal insufficiency without access to haemofiltration or dialysis, acute shock, hyperglycaemia which requires more than 6 units of insulin/h, pathologically elevated serum levels of any of the included electrolytes, general contra-indications to infusion therapy (acute pulmonary oedema, hyperhydration, decompensated cardiac insufficiency, hypotonic dehydration), haemophagocytotic syndrome and unstable conditions. Infants and children under 2 years of age. **Special Warnings and Precautions (see SmPC for full details):** The ability to eliminate fat should be monitored; measure serum triglycerides after a fat free period of 5-6 hours. Serum triglyceride concentration should not exceed 3mmol/l during infusion. One reconstituted bag is for single use. Disturbances in electrolyte and fluid balance should be corrected before starting the infusion. Special clinical monitoring is required at the beginning of any infusion and should any abnormal sign occur, the infusion must be stopped. Strict aseptic precautions should be taken. Kabiven® Peripheral should be given with caution in conditions of impaired lipid metabolism (close monitoring of serum triglycerides mandatory), in patients with metabolic acidosis, increased serum osmolarity, in patients in need of fluid resuscitation and those with a tendency to electrolyte retention. Regularly monitor serum glucose, electrolytes, osmolarity, fluid balance, acid-based status and liver enzyme tests. Amount of supplemental electrolytes to be determined by regular monitoring and consideration of patient's clinical condition. Monitor blood cell count and coagulation when fat given for a longer period. Carefully control phosphate and potassium intake in patients with renal insufficiency. This emulsion is free of vitamins and trace elements, the addition of trace elements and vitamins is always required. Any sign or symptom of anaphylactic reaction necessitates immediate interruption of the infusion. Kabiven® Peripheral contains soya-bean oil and egg phospholipids, which may rarely cause allergic reactions. Cross allergic reaction has been observed between soya-bean and peanut. Fat content may interfere with certain laboratory measurements if blood sampled before fat clearance. Consider trace element dosing as intravenous infusion of amino acids may be accompanied by increased urinary excretion of trace elements, in particular zinc. Careful and slow initiation is recommended in malnourished patients with close monitoring and appropriate dose adjustments. Do not administer with blood or blood products in the same infusion set. Exogenous insulin may be necessary in patients with hyperglycaemia. Thrombophlebitis may occur if peripheral veins used for infusion. **Undesirable Effects:** *Common:* Thrombophlebitis, rise in body temperature. *Uncommon:* Headache, abdominal pain, nausea, vomiting, chills, tiredness, increase in plasma levels of liver enzymes. *Very rare:* Haemolysis, reticulocytosis, hypersensitivity reaction (eg. anaphylactic reaction, skin rash, urticaria), hypotension, hypertension, tachypnoea, priapism. Other adverse reactions can occur (including fat overload syndrome), see SmPC for details. **Legal Category:** POM **Marketing Authorisation Number:** UK: PL 08828/0148. IE: PA 2059/045/004. **Marketing Authorisation Holder**: UK - Fresenius Kabi Limited, Cestrian Court, Eastgate Way, Manor Park, Runcorn, Cheshire WA7 1NT, UK. IE – Fresenius Kabi Deutschland GmbH, Else-Kroener Strasse 1, Bad Homburg v.d.h. 61352, Germany. **Package Size and Cost:** 2400ml £55.72, 1920ml £44.09, 1440ml £30.77. **Further information:** Available from Fresenius Kabi Limited, Cestrian Court, Eastgate Way, Manor Park, Runcorn, Cheshire, WA7 1NT. Tel +44 (0)1928 533 533. **Date of preparation:** February 2021 API/KabivenP-01

Prescribing Information - Kabiven® emulsion for infusion.

Consult the Summary of Product Characteristics for full information. Additional information is available on request. **Active Ingredients:** ***2566ml bag*** Amino acid solution with electrolytes (Vamin 18 Novum) 750ml, Glucose 19% 1316ml, Fat emulsion (Intralipid 20%) 500ml – corresponding to: Purified soybean oil 100g, Glucose (anhydrous) 250g, Alanine 12g, Arginine 8.5g , Aspartic acid 2.6g, Glutamic acid 4.2g, Glycine 5.9g, Histidine 5.1g, Isoleucine 4.2g, Leucine 5.9g, Lysine 6.8g, Methionine 4.2g, Phenylalanine 5.9g, Proline 5.1g, Serine 3.4g, Threonine 4.2g, Tryptophan 1.4g, Tyrosine 0.17g, Valine 5.5g, Calcium chloride 0.56g, Sodium glycerophosphate 3.8g, Magnesium sulphate 1.2g, Potassium chloride 4.5g, Sodium acetate 3.7g. ***2053ml bag*** Amino acid solution with electrolytes (Vamin 18 Novum) 600ml, Glucose 19% 1053ml, Fat emulsion (Intralipid 20%) 400 ml – corresponding to: Purified soybean oil 80g, Glucose (anhydrous) 200g, Alanine 9.6g, Arginine 6.8g, Aspartic acid 2g, Glutamic acid 3.4g, Glycine 4.7g, Histidine 4.1g, Isoleucine 3.4g, Leucine 4.7g, Lysine 5.4g, Methionine 3.4g, Phenylalanine 4.7g, Proline 4.1g, Serine 2.7g, Threonine 3.4g, Tryptophan 1.1g, Tyrosine 0.14g, Valine 4.4g, Calcium chloride 0.44g, Sodium glycerophosphate 3g, Magnesium sulphate 0.96g, Potassium chloride 3.6g, Sodium acetate 2.9g. ***1540ml bag*** Amino acid solution with electrolytes (Vamin 18 Novum) 450ml, Glucose 19% 790ml, Fat emulsion (Intralipid 20%) 300ml – corresponding to: Purified soybean oil 60g, Glucose (anhydrous) 150g, Alanine 7.2g, Arginine 5.1g, Aspartic acid 1.5g, Glutamic acid 2.5g, Glycine 3.6g, Histidine 3.1g, Isoleucine 2.5g, Leucine 3.6g, Lysine 4.1g, Methionine 2.5g, Phenylalanine 3.6g, Proline 3.1g, Serine 2.0g, Threonine 2.5g, Tryptophan 0.86g, Tyrosine 0.1g, Valine 3.3g, Calcium chloride 0.33g, Sodium glycerophosphate 2.3g, Magnesium sulphate 0.72g, Potassium chloride 2.7g, Sodium acetate 2.2g. **Indications:** Parenteral nutrition for patients and children above 2 years of age when oral or enteral nutrition is impossible, insufficient or contraindicated. **Dosage and administration:** The dose should be individualised and the choice of bag size should be made with regard to the patient's clinical condition, body weight and nutritional requirements. Intravenous infusion only into a central vein. Infusion may be continued for as long as required by the patient's clinical condition. Adults – Dose range of 0.10 – 0.20 g nitrogen / kg body weight (bw) / day corresponds to 19 – 38 ml Kabiven / kg bw / day. In obese patients the dose should be based on estimated ideal weight. Children - The ability to metabolise individual nutrients must determine the dosage. For children aged 2 – 10 years, start with a low dose i.e. 12.5 – 25 ml / kg and increase by 10 – 15 ml / kg / day up to maximum dosage of 40 ml / kg / day. For children over 10 years of age the dosage for adults can be applied. The use of Kabiven is not recommended in children under 2 years of age. The infusion rate should not exceed 2.6 ml / kg bw / hour. The recommended infusion period is 12 – 24 hours. Maximum daily dose 40 ml / kg bw / day. The maximum daily dose varies with the clinical condition of the patient and may even change from day to day. **Contraindications:** Hypersensitivity to egg-, soya- or peanut protein or to any of the active substances or excipients. Severe hyperlipaemia, severe liver insufficiency, severe blood coagulation disorders, inborn errors of amino acid metabolism, severe renal insufficiency without access to haemofiltration or dialysis, acute shock, hyperglycaemia which requires more than 6 units of insulin/h, pathologically elevated serum levels of any of the included electrolytes, general contraindications to infusion therapy (acute pulmonary oedema, hyperhydration, decompensated cardiac insufficiency, hypotonic dehydration), haemophagocytotic syndrome and unstable conditions. Infants and children under 2 years of age. **Special warnings and precautions for use (see SmPC for full details):** The patient's ability to eliminate fat should be monitored. It is recommended that this is done by measuring serum triglycerides after a fat free period of 5-6 hours. Serum triglyceride concentration should not exceed 3 mmol/l during infusion. One reconstituted bag is for single use. Disturbances of electrolyte and fluid balance should be corrected before starting the infusion. Special clinical monitoring is required at the beginning of any intravenous infusion and should any abnormal sign occur, the infusion must be stopped. Strict aseptic precautions should be taken. Kabiven should be given with caution in conditions of impaired lipid metabolism; close monitoring of serum triglycerides is mandatory. Monitor serum glucose, electrolytes, osmolarity, fluid balance, acid-base status, liver enzyme tests. Blood cell count and coagulation should be monitored when fat is given for a longer period. Use with caution in metabolic acidosis, lactic acidosis, insufficient cellular oxygen supply, increased serum osmolarity, in patients with a tendency to electrolyte retention, in malnourished patients (careful and slow initiation recommended with close monitoring and appropriate dose adjustments) and patients with renal insufficiency (carefully control phosphate and potassium intake). This emulsion is free of vitamins and trace elements, the addition of trace elements and vitamins is always required. Any sign or symptom of anaphylactic reaction (such as fever, shivering, rash or dyspnoea) should lead to the immediate interruption of the infusion. Kabiven contains soya-bean oil and egg phospholipids, which may rarely cause allergic reactions. Cross allergic reaction has been observed between soya-bean and peanut. Consider trace element dosing, especially during long-term administration. Fat content may interfere with laboratory measurements if blood sampled before fat is cleared from bloodstream. Do not administer with blood in the same infusion set. Exogenous insulin may be necessary in patients with hyperglycaemia. **Undesirable Effects:** *Common* - Rise in body temperature. *Uncommon* - Headache, abdominal pain, nausea, vomiting, chills, tiredness, increase in plasma levels of liver enzymes. *Very rare* - Haemolysis, reticulocytosis, hypersensitivity reactions (eg. anaphylactic reaction, skin rash, urticaria), hypotension, hypertension, tachypnoea, priapism. Other adverse reactions can occur (including fat overload syndrome); see Summary of Product Characteristics for details. **Legal Category:** POM. **Marketing Authorisation Numbers:** UK: PL 08828/0131. IE: PA 2059/045/003 (Biofine bag). **Marketing Authorisation Holder:** UK - Fresenius Kabi Limited, Cestrian Court, Eastgate Way, Manor Park, Runcorn, Cheshire, WA7 1NT, UK. IE – Fresenius Kabi Deutschland GmbH, Else-Kroener Strasse 1, Bad Homburg v.d.H. 61352, Germany. **Package Size and Cost:** 2566mls £59.92, 2053mls £57.42, 1540mls £44.09. **Further information:** Available from Fresenius Kabi Limited, Cestrian Court, Eastgate Way, Manor Park, Runcorn, Cheshire, WA7 1NT. Tel +44 (0)1928 533 533. **Date of preparation:** October 2020 API/Kabiven-01

Notes

Adverse events should be reported.
Reporting forms and information can be found at:
yellowcard.mhra.gov.uk
www.hpra.ie/homepage/about-us/report-an-issue

Adverse events should be reported to Fresenius Kabi Limited,
Cestrian Court, Eastgate Way, Manor Park, Runcorn, Chesire, WA7 1NT
Tel: +44 (0)1928 533 533

FRESENIUS KABI
caring for life

Fresenius Kabi Limited
Fresenius Kabi Ireland, Unit 3B Fingal Bay,
Balbriggan, Co. Dublin, Ireland
T: +353 (0)1 8413030 F: +353 (0)1 8496949
www.fresenius-kabi.ie

Date of preparation: May 2023
Job code: IE-3CB-2300006