FRESENIUS KABI

caring for life

*Smof*Kabiven®, SmofKabiven Extra Nitrogen® & Kabiven® Parenteral Nutrition

- The convenient solution to your patients' nutritional requirements
- Weekend feeding
- Supplemental feeding

*Smof*Kabiven® Range – Total Bag Contents

Regimen	Shelf Life	*Route	Volume ml	Total Kcal	Non-Protein Kcal	g/ Nitrogen	g/CHO	g/Fat	Na mmols	K mmols	Ca mmols	Mg mmols	**PO_4 mmols	Zinc mmols
***Smof*Kabiven®**														
*Smof*Kabiven® Peripheral 9.8	2 yrs	P	1904	1300	1100	9.8	135	54	48	36	3	6	15.6	0.05
*Smof*Kabiven® 4	2 yrs	C	493	550	450	4	63	19	20	15	1.3	2.5	6	0.02
*Smof*Kabiven® 8	2 yrs	C	986	1100	900	8	125	38	40	30	2.5	5	12	0.04
*Smof*Kabiven® 8 Electrolyte Free	2 yrs	C	986	1100	900	8	125	38	nil	nil	nil	nil	2.8	nil
*Smof*Kabiven® 12	2 yrs	C	1477	1600	1300	12	187	56	60	45	3.8	7.5	19	0.06
*Smof*Kabiven® 12 Electrolyte Free	2 yrs	C	1477	1600	1300	12	187	56	nil	nil	nil	nil	4.2	nil
*Smof*Kabiven® 16	2 yrs	C	1970	2200	1800	16	250	75	80	60	5	10	25	0.08
*Smof*Kabiven® 16 Electrolyte Free	2 yrs	C	1970	2200	1800	16	250	75	nil	nil	nil	nil	5.6	nil

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

*Smof*Kabiven® Extra Nitrogen Range – Total Bag Contents

Regimen	Shelf Life	*Route	Volume ml	Total Kcal	Non-Protein Kcal	g/ Nitrogen	g/CHO	g/Fat	Na mmols	K mmols	Ca mmols	Mg mmols	**PO_4 mmols	Zinc mmols
***Smof*Kabiven®**														
*Smof*kabiven® Extra Nitrogen 1012ml	2 years	c	1012	900	635	10.6	85.7	29.2	41.3	30.9	2.6	5.2	12.9	0.04
*Smof*kabiven® Extra Nitrogen 1518ml	2 years	c	1518	1350	952	15.9	129	43.8	61.9	46.4	3.9	7.7	19.3	0.06
*Smof*kabiven® Extra Nitrogen 2025ml	2 years	c	2025	1800	1270	21.2	171	58.4	82.6	61.9	5.2	10.3	25.8	0.08
*Smof*kabiven® Extra Nitrogen EF 1012ml	2 years	c	1012	900	635	10.6	85.7	29.2	nil	nil	nil	nil	nil	nil
*Smof*kabiven® Extra Nitrogen EF 1518ml	2 years	c	1518	1350	952	15.9	129	43.8	nil	nil	nil	nil	nil	nil
*Smof*kabiven® Extra Nitrogen EF 2025ml	2 years	c	2025	1800	1270	21.2	171	58.4	nil	nil	nil	nil	nil	nil

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

Kabiven® Range – Total Bag Contents

Regimen	Shelf Life	*Route	Volume ml	Total Kcal	Non-Protein Kcal	g/ Nitrogen	g/CHO	g/Fat	Na mmols	K mmols	Ca mmols	Mg mmols	**PO_4 mmols
Kabiven®													
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

* Route: C= Central. P= Peripheral. ** Including amount provided by the lipid source.

MAXIMUM ADDITIONS: Additions up to a total. Electrolyte ranges: 7 day stability.

Product Range Maximum Additions	Dipeptiven ml	Na mmols	K mmols	Mg mmols	Ca mmols	*PO_4 mmols (As Sodium Glycerophosphate 21.6%)	Zinc mmols
*Smof*Kabiven® Peripheral 9.8	300	300	300	10	10	30 (60)	0.3
*Smof*Kabiven® 4	100	75	75	2.5	2.5	7.5 (15)	0.1
*Smof*Kabiven® 8	150	150	150	5	5	15 (30)	0.2
*Smof*Kabiven® 8 Electrolyte Free	150	150	150	5	5	15 (30)	0.2
*Smof*Kabiven® 12	250	225	225	7.5	7.5	22.5 (45)	0.25
*Smof*Kabiven® 12 Electrolyte Free	250	225	225	7.5	7.5	22.5 (45)	0.25
*Smof*Kabiven® 16	300	300	300	10	10	30 (60)	0.3
*Smof*Kabiven® 16 Electrolyte Free	300	300	300	10	10	30 (60)	0.3
*Smof*Kabiven® Extra Nitrogen 1012ml	300	150	150	5	5	15 (30)	0.2
*Smof*Kabiven® Extra Nitrogen 1518ml	300	225	225	7.5	7.5	22.5 (45)	0.3
*Smof*Kabiven® Extra Nitrogen 2025ml	300	300	300	10	10	30 (60)	0.4

*Including amount provided by the lipid source.
The above limits include any amounts provided by the constituents of the bag. Please note that any additions are outside the scope of the Product Authorisation.

MAXIMUM ADDITIONS: Additions up to a total. Electrolyte ranges: 7 day stability.

Product Range Maximum Additions	Dipeptiven ml	Na mmols	K mmols	Mg mmols	Ca mmols	*PO_4 mmols (As Sodium Glycerophosphate 21.6%)	Zinc mmols
*Smof*Kabiven® Extra Nitrogen EF 1012 ml	300	150	150	5	5	15 (30)	0.2
*Smof*Kabiven® Extra Nitrogen EF 1518 ml	300	225	225	7.5	7.5	22.5 (45)	0.3
*Smof*Kabiven® Extra Nitrogen EF 2025 ml	300	300	300	10	10	30 (60)	0.4
Kabiven® Peripheral 5	200	216	216	7.2	7.2	21.5 (43)	0.3
Kabiven® Peripheral 7	300	288	288	9.6	9.6	29 (58)	0.4
Kabiven® Peripheral 9	300	360	360	12	12	36 (72)	0.4
Kabiven® 8	200	231	231	8	8	23 (46)	0.25
Kabiven® 11	300	308	308	10	10	31 (62)	1.0
Kabiven® 14	300	385	385	13	13	38 (76)	1.25

*Including amount provided by the lipid source.
The above limits include any amounts provided by the constituents of the bag. Please note that any additions are outside the scope of the Product Authorisation.

*Smof*Kabiven® Range – Ordering Information

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

Item Description	Product Code	Case Quantity
*Smof*Kabiven® Extra Nitrogen 1012ml	833061220	4
*Smof*Kabiven® Extra Nitrogen 1518ml	833079220	4
*Smof*Kabiven® Extra Nitrogen 2025ml	833087220	4
*Smof*Kabiven® Extra Nitrogen EF 1012ml	833020220	4
*Smof*Kabiven® Extra Nitrogen EF 1518ml	833004220	4
*Smof*Kabiven® Extra Nitrogen EF 2025ml	833012220	4

Kabiven® Range – 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.

Kabiven® 3 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.

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.

Abbreviated prescribing information – Kabiven® emulsion for infusion

Consult the Summary of Product Characteristics for full information. Additional information is available on request. **Kabiven® emulsion for infusion. 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 (as anahydrous) 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 (as anahydrous) 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), Glucose 19% 790mls, Fat emulsion (Intralipid 20%) 300ml – corresponding to: Purified soybean oil 60g. Glucose (as anahydrous) 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. Recommended Dosage for Adults- the nitrogen requirements for maintenance of body protein mass depend on the patients' condition (e.g. nutritional state and degree of catabolic stress). The total energy requirement depends on the patient's clinical condition and is most often between 25-35kcal/kg bw/day. To provide total parenteral nutrition, trace elements and vitamins should be given additionally. Recommended Dosage for Children- the ability to metabolise individual nutrients must determine the dosage. 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 maximum infusion rate for glucose is 0.25g/kg/hr. Amino acid dosage should not exceed 0.1g/kg/h. Fat dosage should not provide more than 0.15/kg/h. The infusion rate should not exceed 2.6ml/kg bw/hour (corresponding to 0.25g glucose, 0.09g amino acid and 0.1g fat/kg bw). The recommended infusion rate is 12-24 hours. Maximum daily dose 40ml/kg bw/day. This is equal to one bag (2566ml) to a 64kg patient and will provide 1.3g amino acid/kg/day (0.21 N/kg/day), 31kcal/kg/day non-protein energy 3.9g glucose/kg/day and 1.6 fat/kg/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, soy 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, 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. It is recommended that this is done by measuring serum triglyceride after a fat free period of 5-6 hours. 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. Kabiven® should be given with caution in conditions of impaired lipid metabolism. 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 soybean oil and egg phospholipid, which may rarely cause allergic reactions. Cross allergic reaction has been observed between soybean and peanut. **Interactions:** Some drugs like insulin and heparin may interfere with the body's lipase system. Soybean oil has a natural content of Vitamin K1. This may interfere with the therapeutic effect of coumarin derivatives which should be closely monitored in patients treated with such drugs. There are no clinical data to show that any of the mentioned interactions are of definite clinical relevance. **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. **Legal Category:** POM. Marketing Authorisation Number: *UK:* PL 08828/0131, *IE:* PA 566/3/3. **Marketing Authorisation Holder:** Fresenius Kabi Limited, Cestrian Court, Eastgate Way, Manor Park, Runcorn, Cheshire, WA7 1NT, UK. **Package Size and Cost:** 2566mls £59.92, 2053mls £57.42, 1540mls £44.09. **Adverse events should always be reported.** Reporting forms and information can be found at www.yellowcard.gov.uk and for Ireland at www.hpra.ie. Adverse events should also be reported to Fresenius Kabi Limited (Pharmacovigilance.GB@fresenius-kabi.com) **Date of Revision:** March 2019.

Abbreviated 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 500ml (Vamin® 18 Novum), Glucose 11% 1475ml, 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* Amino acids and electrolytes (Vamin® 18 Novum) 400ml, Glucose 19% 1180ml, 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* Amino acids and electrolytes (Vamin®18 Novum) 300ml, Glucose 19% 885ml, Fat emulsion (Intralipid 20%) 255ml – corresponding to: Purified soybean oil 51g, Glucose (as anahydrous) 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 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 total energy requirement depends on the patient's clinical condition is the most often between 20-30kcal/kg bw/day. To provide total parenteral nutrition, trace elements and vitamins should be given additionally. Children- the ability to metabolise individual nutrients must determine the dosage. 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 maximum infusion rate for glucose is 0.25g/kg/hr. Amino acid dosage should not exceed 0.1g/kg/h. Fat dosage should not provide more than 0.15/kg/h. The infusion rate should not exceed 3.7ml/kg bw/hour (corresponding to 0.25g glucose, 0.09g amino acid and 0.13g fat/kg bw). The recommended infusion rate 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, 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. It is recommended that this is done by measuring serum triglyceride after a fat free period of 5-6 hours. 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. Kabiven® should be given with caution in conditions of impaired lipid metabolism. 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 soybean oil and egg phospholipid, which may rarely cause allergic reactions. Cross allergic reaction has been observed between soybean and peanut. **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. **Legal Category:** POM. **Marketing Authorisation Number:** *UK:* PL 08828/0148, *IE:* PA 566/3/4. **Marketing Authorisation Holder:** Fresenius Kabi Limited, Cestrian Court, Eastgate Way, Manor Park, Runcorn, Cheshire, WA7 1NT, UK. **Package Size and Cost:** 2400ml £55.72, 1920ml £44.09, 1440mls £30.77. **Adverse events should always be reported.** Reporting forms and information can be found at www.yellowcard.gov.uk and for Ireland at www.hpra.ie. Adverse events should be also be reported to Fresenius Kabi Limited (Pharmacovigilance.GB@fresenius-kabi.com) **Date of Revision:** March 2019.

Abbreviated Prescribing information - SmofKabiven® Central emulsion for infusion.

Consult the Summary of product Characteristics for full information. Additional information is available on request. **SmofKabiven® Central emulsion for infusion. Active Ingredients:** *1970ml bag* Amino acid solution with electrolytes 1000ml, Glucose 42% 595ml, Fat emulsion 375ml - corresponding to: Fat 75g, Glucose 250g, Alanine 14.0g, Arginine 12.0g, Glycine 11g, 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 0.4g, Valine 6.2g, Calcium chloride 0.56g, Sodium Glycerophosphate 4.2, Magnesium sulphate 1.2g, Potassium chloride 4.5g, Sodium acetate 3.4g, Zinc sulphate 0.013g. *1477ml bag* Amino acid solution with electrolytes 750ml, Glucose 42% 446ml, Fat emulsion 281ml - corresponding to: Fat 56g, Glucose 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 0.42g, Sodium Glycerophosphate 3.1g, Magnesium sulphate 0.90g, Potassium chloride 3.4g, Sodium acetate 2.6g, Zinc sulphate 0.0097g. *986ml bag* Amino acid solution with electrolytes 500ml, Glucose 42% 298ml, Fat emulsion 188ml - corresponding to: Fat 38g, Glucose 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 0.28g, Sodium Glycerophosphate 2.1g, Magnesium sulphate 0.60g, Potassium chloride 2.2g, Sodium acetate 1.7g, Zinc sulphate 0.0065g. *493ml bag* Amino acid solution with electrolytes 250ml, Glucose 42% 149ml, Fat emulsion 94ml, Alanine 3.5g, Arginine 3g, 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, Trytophan 0.5g, Tyrosine 0.10g, Valine 1.6g, Calcium Chloride 0.14g, Sodium Glycerophosphate 1.1g, Magnesium sulphate 0.3g, Potassium chloride 1.2g, Sodium acetate 0.9g, Zinc sulphate 0.0033g. **Indications:** Parenteral nutrition for adult patients when oral or enteral nutrition is impossible, insufficient or contraindicated. **Dosage and Administration:** Intravenous infusion into a central line. The dose should be individualised to the patient's clinical condition, body weight and nutritional requirements. The recommended maximum daily dose is 35ml/kg bw/day. The infusion rate should not exceed 2.0 ml/kg bw/hour (corresponding to 0.25g glucose, 0.1g amino acid, and 0.08g fat/kg bw/h). The recommended infusion period is 14-24 hours. **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 of any of the included electrolytes, general contraindications to infusion therapy, haemophagocytotic syndrome and unstable conditions. **Special Warnings and Precautions (see SmPC for full details):** The ability to eliminate fat should be monitored. 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. Standard precautions relating to infusion therapy should be taken. Not suitable for use in new-borns or infants below 2 years of age. No clinical experience in children (age 2 years to 11 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 (anaphylactic or anaphylactoid reactions, skin rash, urticaria, flush, headache) heat or cold sensation, paleness, cyanosis, pain in the neck, back, bones, chest and loins. **Legal Category:** POM. **Marketing Authorisation Number:** *UK:* PL 08828/0187, *IE:* PA 566/46/1 **Marketing Authorisation Holder:** Fresenius Kabi Limited, Cestrian Court, Eastgate Way, Manor Park, Runcorn, Cheshire, WA7 1NT, UK. **Package Size and Cost:** 1970ml bag £67.73, 1477ml bag £64.05, 986ml bag £63.58, 493mls £58.00. **Adverse events should always be reported.** Reporting forms and information can be found at www.yellowcard.gov.uk and for Ireland at www.hpra.ie. Adverse events should be also be reported to Fresenius Kabi Limited (Pharmacovigilance.GB@fresenius-kabi.com) **Date of Revision:** March 2019.

Abbreviated Prescribing information- SmofKabiven® Electrolyte Free emulsion for infusion.

Consult the Summary of Product Characteristics for full information. Additional information is available on request. **SmofKabiven® Electrolyte Free emulsion for infusion. Active Ingredients:** *1970ml bag* Amino acid solution 1000ml, Glucose 42% 595ml, Fat emulsion 375ml - corresponding to: Fat 75g, Glucose 250g, Alanine 14.0g, Arginine 12.0g, Glycine 11g, 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 0.4g, Valine 6.2g. *1477ml bag* Amino acid solution 750ml, Glucose 42% 446ml, Fat emulsion 281ml - corresponding to: Fat 56g, Glucose (as 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, Fat emulsion 188ml - corresponding to: Fat 38g, Glucose (as monohydrate) 125g, Alanine 7.0g, Arginine 6.0, 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 adult patients when oral or enteral nutrition is impossible, insufficient or contraindicated. **Dosage and Administration:** Intravenous infusion into a central line. The dose should be individualised to the patient's clinical condition, body weight and nutritional requirements. The recommended maximum daily dose is 35ml/kg bw/day. The infusion rate should not exceed 2.0 ml/kg body weight/hour (corresponding to 0.25g glucose, 0.1g amino acid, and 0.08g fat/kg body weight/hour). The recommended infusion period is 14-24 hours. **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 of any of the included electrolytes, general contraindications to infusion therapy, haemophagocytotic syndrome and unstable conditions. **Special Warnings and Precautions (see SmPC for full details):** The ability to eliminate fat should be monitored. Should be given with caution in conditions of impaired lipid metabolism. This medicinal product contains soya-bean oil, fish oil and egg phospholipids, which may cause allergic reactions. Cross allergic reaction has been observed between soya-bean and peanut. Any sign or symptom of anaphylactic reaction (such as fever, shivering, rash or dyspnoea) should lead to immediate interruption of the infusion. Due to composition of the amino acid solution, this infusion is not suitable for use in new-borns or infants below 2 years of age. No clinical experience in children (age 2 years to 11 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, dyspnea, hypotension, hypertension, hypersensitivity reactions (eg. anaphylactic or anaphylactoid reactions, skin rash, urticaria, flush, headache), heat or cold sensation, paleness, cyanosis, pain in the neck, back, bones, chest and loins. **Legal Category:** POM. **Marketing Authorisation Number:** *UK:* PL 08828/0188, *IE:* PA 566/47/2. **Marketing Authorisation Holder:** Fresenius Kabi Limited, Cestrian Court, Eastgate Way, Manor Park, Runcorn, Cheshire, WA7 1NT, UK. **Package Size and Cost:** 1970ml £67.73, 1477ml £64.05, 986ml bag £63.58. **Adverse events should always be reported.** Reporting forms and information can be found at www.yellowcard.gov.uk and for Ireland at www.hpra.ie. Adverse events should be also be reported to Fresenius Kabi Limited (Pharmacovigilance.GB@fresenius-kabi.com) **Date of Revision:** March 2019.

Abbreviated Prescribing information - SmofKabiven® Peripheral emulsion for infusion.

Consult the Summary of Product Characteristics for full information. Additional information is available on request. **SmofKabiven® Peripheral emulsion for infusion. Active Ingredients:** *1904ml bag* Amino acid solution with electrolytes 600ml, Glucose 13% 1036ml, Fat emulsion 268ml - corresponding to: Fat 54g. 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 0.34g, Sodium Glycerophosphate 2.5g, Magnesium sulphate 0.72g, Potassium chloride 2.7g, Sodium acetate 2.0g, Zinc sulphate 0.008g **Indications:** Parenteral nutrition for adult patients when oral or enteral nutrition is impossible, insufficient or contraindicated. **Dosage and Administration:** Intravenous infusion into a peripheral line or central line. The dose should be individualised to the patient's clinical condition, body weight and nutritional requirements. The recommended maximum daily dose is 40ml/kg bw/day. The infusion rate should not exceed 3.0 ml/kg body weight/hour (corresponding to 0.21g glucose, 0.1g amino acid, and 0.08g fat/kg body weight/hour). The recommended infusion period is 14-24 hours. **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 of any of the included electrolytes, general contraindications to infusion therapy, haemophagocytotic syndrome and unstable conditions. Special Warnings and Precautions (see SmPC for full details): The ability to eliminate fat should be monitored. 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. Standard precautions relating to infusion therapy should be taken. Not suitable for use in new-borns or infants below 2 years of age. No clinical experience in children (age 2 years to 11 years). **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 (eg. anaphylactic or anaphylactoid reactions, skin rash, urticaria, flush, headache), heat or cold sensation, paleness, cyanosis, pain in the neck, back, bones, chest and loins. **Legal Category:** POM. **Marketing Authorisation Number:** *UK:* PL 08828/0213, *IE:* PA 566/051/01,02 **Marketing Authorisation Holder:** Fresenius Kabi Limited, Cestrian Court, Eastgate Way, Manor Park, Runcorn, Cheshire, WA7 1NT, UK. **Package Size and Cost:** 1904ml bag £63.84. **Adverse events should always be reported.** Reporting forms and information can be found at www.yellowcard.gov.uk and for Ireland at www.hpra.ie. Adverse events should be also be reported to Fresenius Kabi Limited (Pharmacovigilance.GB@fresenius-kabi.com). **Date of Revision:** March 2019.

Abbreviated Prescribing Information - SmofKabiven® Extra Nitrogen, Emulsion For Infusion.

Consult the Summary of Product Characteristics for full information. Additional information is available on request. **SmofKabiven® Extra Nitrogen, Emulsion for Infusion. 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. 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. For 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). 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. 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, hemophagocytotic syndrome, unstable conditions, neonates and infants under 2 years of age. **Special warnings and precautions for use:** Use with caution in conditions of impaired lipid metabolism, in patients with a tendency to retain electrolytes, in lactic acidosis, insufficient cellular oxygen supply and increased serum osmolarity. Contains soya-bean oil, fish oil and egg phospholipids which may rarely cause allergic reactions. Cross allergic reaction has been seen between soya-bean and peanut. 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 or symptom occur, the infusion must be stopped. 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. Other precautions may be necessary – see SmPC for details. **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, see SmPC for details. **Legal Category:** POM. **Marketing Authorisation Number:** *UK:* PL 08828/0268, *IE:* PA 0566/076/1. **Marketing Authorisation Holder:** Fresenius Kabi Limited, Cestrian Court, Eastgate Way, Manor Park, Runcorn, Cheshire, WA7 1NT, UK. **Package Size and Cost:** 2025ml £89.00, 1518ml £80.00, 1012ml £75.00. **Adverse events should always be reported.** Reporting forms and information can be found at https://yellowcard.mhra.gov.uk and for Ireland at www.hpra.ie. Adverse events should also be reported to Fresenius Kabi Limited (Pharmacovigilance.GB@fresenius-kabi.com). **Date of Preparation:** March 2019.

Abbreviated 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. **SmofKabiven® Extra Nitrogen Electrolyte Free, Emulsion for Infusion. 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. 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. For 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). 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. To provide total parenteral nutrition, trace elements, electrolytes and vitamins 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, hemophagocytotic syndrome, unstable conditions, neonates and infants under 2 years of age. **Special warnings and precautions for use:** Use with caution in conditions of impaired lipid metabolism, in lactic acidosis, insufficient cellular oxygen supply and increased serum osmolarity. Contains soya-bean oil, fish oil and egg phospholipids which may rarely cause allergic reactions. Cross allergic reaction has been seen between soya-bean and peanut. Electrolyte additions should be governed by the clinical condition of the patient and by frequent monitoring. Special clinical monitoring is required at the beginning of any infusion and should any abnormal sign or symptom occur, the infusion must be stopped. 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. Other precautions may be necessary – see SmPC for details. **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, see SmPC for details. **Legal Category:** POM Marketing **Authorisation Number:** *UK:* PL 08828/0269, *IE:* PA 0566/076/2. **Marketing Authorisation Holder:** Fresenius Kabi Limited, Cestrian Court, Eastgate Way, Manor Park, Runcorn, Cheshire, WA7 1NT, UK. **Package Size and Cost:** 2025ml £89.00, 1518ml £80.00, 1012ml £75.00. **Adverse events should always be reported.** Reporting forms and information can be found at https://yellowcard.mhra.gov.uk and for Ireland at www.hpra.ie. Adverse events should also be reported to Fresenius Kabi Limited (Pharmacovigilance.GB@fresenius-kabi.com). **Date of Preparation:** March 2019.

Adverse events should be reported. Reporting forms and information can be found at www.yellowcard.gov.uk and for Ireland at www.hpra.ie.
Adverse events should also be reported to Fresenius Kabi Limited. Email: pharmacovigilance.GB@fresenius-kabi.com Date of Revision: January 2019.

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