Prescribing information

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SmofKabiven® Central Emulsion for Infusion (amino acids, electrolytes, glucose, lipid emulsion)

SMOFKABIVEN CENTRAL, EMULSION FOR INFUSION

Active ingredients: 2463ml bag Amino acid solution with electrolytes 1250ml, Glucose 42% 744ml, Lipid emulsion 469ml – corresponding to: Soya-bean oil, refined 28.1g, Medium-chain triglycerides 28.1g, Olive oil, refined 23.4g, Fish oil, rich in omega-3-acids 14.0g, Glucose (monohydrate) 313g, Alanine 17.5g, Arginine 15.0g, Glycine 13.8g, Histidine 3.7g, Isoleucine 6.2g, Leucine 9.4g, Lysine (as acetate) 8.4g, Methionine 5.4g, Phenylalanine 6.4g, Proline 14.0g, Serine 8.1g, Taurine 1.2g, Threonine 5.4g, Tryptophan 2.5g, Tyrosine 0.49g, Valine 7.6g, Calcium chloride (as dihydrate) 0.69g, Sodium glycerophosphate (as hydrate) 5.2g, Magnesium sulphate (as heptahydrate) 1.5g, Potassium chloride 5.7g, Sodium acetate (as trihydrate) 4.2g, Zinc sulphate (as heptahydrate) 0.016g **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, Sodiumacetate (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. The recommended maximum daily dose is 35ml/kg bw/day. For adults, the 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. For 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. In 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, hemophagocytotic syndrome, unstable conditions, infants and children 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 towards electrolyte retention, in lactic acidosis, increased serum osmolarity and insufficient cellular oxygen supply. Contains soyabean oil, fish oil and egg phospholipids which may rarely cause allergic reactions. Cross allergic react ion has been observed 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 occur, the infusion must be stopped. Monitor 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 (see SmPC). IV amino acid infusion increases urinary excretion of trace elements; consider when trace element dosing. No clinical experience in children (aged 2 to 16/18 years). Other precautions may be necessary – see SmPC for details. **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**: PL08828/0187. **Marketing Authorisation Holder**: Fresenius Kabi Limited, Cestrian Court, Eastgate Way, Manor Park, Runcorn, Cheshire, WA7 1NT, UK. **Package size and cost**: 2463ml £75.00, 1970ml £67.73, 1477ml £64.05,986ml £63.58, 493ml £58.00. **Further information**: See the SmPC for further details. **Adverse events should be reported**. Reporting forms and information can be found at **https://yellowcard.mhra.gov.uk**. Adverse events should also be reported to Fresenius Kabi Limited. **Date of preparation** : November 2017.

SmofKabiven® Electrolyte Free Central Emulsion for Infusion (amino acids, glucose, lipid emulsion)

SMOFKABIVEN ELECTROLYTE FREE CENTRAL EMULSION FOR INFUSION 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-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 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 35ml/kg bw/day. For adults, the 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. For 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. In adolescents (12-16/18 years), SmofKabiven Electrolyte Free Central can be used 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-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, infants and children under 2 years of age. **Special warnings and precautions for use**: 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. 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 occur, the infusion must be stopped. Monitor 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. No clinical experience in children (age 2 to 16/18 years). Other precautions may be necessary – see SmPC for details. **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**: PL 08828/0188. **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 £63.58. **Further information**: See the SmPC for further details. **Adverse events should be reported**. Reporting forms and information can be found at **https://yellowcard.mhra.gov.uk**. Adverse events should also be reported to Fresenius Kabi Limited. **Date of preparation**: November 2017.

SmofKabiven® Peripheral Emulsion for Infusion (amino acids, electrolytes, glucose, lipid emulsion)

SMOFKABIVEN PERIPHERAL EMULSION FOR INFUSION. 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-acids, 8g, Glucose (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. The recommended maximum daily dose is 40ml/kg bw/day. The infusion rate should not exceed 3.0ml/kg bw/hour (corresponding to 0.21g glucose, 0.1g amino acids, and 0.08g lipids/kg bw/hour). For adults, the recommended infusion period is 14–24 hours. For children (2-11 years) the recommended infusion period is 12-24 hours. In children, if using the recommended maximum daily dose, the dose should be infused over at least 13 hours. In adolescents (12-16/18 years) SmofKabiven 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 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, infants and children 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 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. 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, the infusion must be stopped. Monitor 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. Thrombophlebitis may occur if peripheral veins are used. No clinical experience in children (age 2 to 16/18 years). Other precautions may be necessary – see SmPC for details. **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:** PL 08828/0213. **Marketing Authorisation Holder:** Fresenius Kabi Limited, Cestrian Court, Eastgate Way, Manor Park, Runcorn, Cheshire, WA7 1NT, UK. **Package size and cost:** 1904ml £63.84. **Further information:** See the SmPC for further details. **Adverse events should be reported.** Reporting forms and information can be found at **https://yellowcard.mhra.gov.uk.** Adverse events should also be reported to Fresenius Kabi Limited. **Date of preparation:** November 2017.

SmofKabiven® extra Nitrogen Emulsion for Infusion (amino acids, electrolytes, glucose, lipid emulsion)

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, Valin e 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 recommen ded 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, hemo phagocytotic 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. **Side 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** PL 08828/0268. **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. Further Information: See the SmPC for further details. **Adverse events should be reported** . Reporting forms and information can be found at **https://yellowcard.mhra.gov.uk** . Adverse events should also be reported to Fresenius Kabi Limited. **Date of Preparation**: January 2018.

SmofKabiven® extra Nitrogen Electrolyte Free Emulsion for Infusion (amino acids, glucose, lipid emulsion)

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 inconditions 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. Side **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**: PL 08828/0269. **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. **Further Information**: See the SmPC for further details. **Adverse events should be reported**. Reporting forms and information can be found at **https://yellowcard.mhra.gov.uk**. Adverse events to Fresenius Kabi Limited. should also be reported. **Date of Preparation.** January 2018.

SmofKabiven® Low Osmo Peripheral Emulsion for Infusion (amino acids, electrolytes, glucose, lipid emulsion)

SMOFKABIVEN LOW OSMO PERIPHERAL, EMULSION FOR INFUSION 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) and nutritional requirements. The recommended maximum daily dose is 40ml/kg bw/day. Adult infusion rate should not exceed 3.7ml/kg bw/hour (corresponding to 0.25g glucose, 0.09g amino acids, and 0.13g lipids/kg bw/hour). The recommended infusion period is 12-24 hours. For children (2-11 years), the recommended maximum infusion rate is 4.0ml/kg bw/hour (corresponding to 0.27g glucose, 0.10g amino acids, and 0.14g lipids/kg/hour). The recommended infusion period is 12-24 hours. At the recommended maximum infusion rate, do not use an infusion period longer than 10 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 haemofiltration or dialysis, acute shock, uncontrolled hyperglycaemia, pathologically elevated serum levels of any of the included electrolytes general contraindications to infusion therapy, haemophagocytotic 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. **Side 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** PL 08828/0274. **Marketing Authorisation Holder** : Fresenius Kabi Limited, Cestrian Court, Eastgate Way, Manor Park, Runcorn, Cheshire, WA7 1NT, UK. **Package Size and Cost**: 2500ml £68.00, 1950ml £61.00, 1400ml £58.00 **Further Information**: See the SmPC for further details. **Adverse events should be reported**. Reporting forms and information can be found at **https://yellowcard.mhra.gov.uk.** Adverse events should also be reported to Fresenius Kabi Limited. **Date of Preparation**: May 2019.

Kabiven® Emulsion for Infusion (amino acids, electrolytes, glucose, lipid emulsion)

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 (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 (as dihydrate) 0.56g, Sodium glycerophosphate (as hydrated) 3.8g, Magnesium sulphate (as heptahydrate) 1.2g, Potassium chloride 4.5g, Sodium acetate (as trihydrate) 3.7g **2053ml bag** Amino acid solution with electrolytes (Vamin 18 Novum) 600ml, Glucose 19% 1053ml, Fat emulsion (Intralipid 20%) 400ml - 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 (as dihydrate) 0.44g, Sodium glycerophosphate (as hydrated) 3g, Magnesium sulphate (as heptahydrate) 0.96g, Potassium chloride 3.6g, Sodium acetate (as trihydrate) 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 (as dihydrate) 0.33g, Sodium glycerophosphate (as hydrated) 2.3g, Magnesium sulphate (as heptahydrate) 0.72g, Potassium chloride 2.7g, Sodium acetate (as trihydrate) 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**: Intravenous infusion only into a central vein. The dose should be individualised to the patient's clinical condition, body weight and nutritional requirements. Recommended maximum daily dose – 40ml/kg body weight (bw)/day. Maximum infusion rate – 2.6ml/kg bw/hour (corresponding to 0.25g glucose, 0.09g amino acids and 0.1g fat/kg bw). The recommended infusion period is 12-24 hours. For children aged 2-10 years, start with a low dose 12.5-25ml/kg and increase by 10-15ml/kg/day to a maximum of 40ml/kg/day. For children over 10 years the adult dosage can be applied. The addition of trace elements and vitamins is always required. **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 hemofiltration or dialysis, acute shock, hyperglycaemia that requires more than 6 units insulin/h, pathologically elevated serum levels of any of the included electrolytes, general contraindications to infusion therapy, hemophagocytotic syndrome, unstable conditions, infants and children 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 towards electrolyte retention, in metabolic acidosis, lactic acidosis, insufficient cellular oxygen supply and increased serum osmolarity. The bag size should be carefully chosen and volumes adjusted according to hydration and nutritional status. Contains soya-bean oil and egg phospholipids which may rarely cause allergic reactions. Cross allergic reaction has been observed 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 occur, the infusion must be stopped. Monitor serum glucose, electrolytes, osmolarity, fluid balance, acid-base balance and liver enzyme tests. When fat is given for a longer period, blood cell count and coagulation should be monitored. Other precautions may be necessary – see SmPC for details. **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, hypotension, hypertension, tachypnoea, priapism. Other adverse reactions can occur (including fat overload syndrome), see SmPC for details. **Legal Category**: POM **Marketing Authorisation Number**: PL 08828/0131. Marketing Authorisation Holder: Fresenius Kabi Limited, Cestrian Court, Eastgate Way, Manor Park, Runcorn, Cheshire, WA7 1NT, UK. Package Size and Cost: 2566ml £59.92, 2053ml £57.42, 1540ml £44.09. **Further Information**: See the SmPC for further details. **Adverse events should be reported**. Reporting forms and information can be found at **https://yellowcard.mhra.gov.uk**. Adverse events should also be reported to Fresenius Kabi Limited. **Date of preparation**: March 2019.

Kabiven® Peripheral Emulsion for Infusion (amino acids, electrolytes, glucose, lipid emulsion)

KABIVEN PERIPHERAL EMULSION FOR INFUSION. Active Ingredients:
2400ml bag Amino acids and electrolytes (Vamin 18 Novum) 500ml, Glucose (Glucose 11%) 1475ml, Fat emulsion (Intralipid 20%) 425ml – corresponding to: Purified soybean oil 85g, Glucose (anhydrous) 162g, Alanine 8.0g, Arginine 5.6g, Aspartic acid 1.7g, Glutamic acid 2.8g, Glycine 4.0g, Histidine 3.4g, Isoleucine 2.8g, Leucine 4.0g, Lysine 4.5g, Methionine 2.8g, Phenylalanine 4.0g, Proline 3.4g, Serine 2.2g, Threonine 2.8g, Tryptophan 0.95g, Tyrosine 0.12g, Valine 3.6g, Calcium chloride (as dihydrate) 0.37g, Sodium glycerophosphate (hydrated) 2.5g, Magnesium sulphate (as heptahydrate) 0.80g, Potassium chloride 3.0g, Sodium acetate (as trihydrate) 2.4g. **1920ml bag** Amino acids and electrolytes (Vamin 18 Novum) 400ml, Glucose (Glucose 11%) 1180ml, Fat emulsion (Intralipid 20%) 340ml – corresponding to: Purified soybean oil 68g, Glucose (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 (as dihydrate) 0.30g, Sodium glycerophosphate (hydrated) 2.0g, Magnesium sulphate (as heptahydrate) 0.64g, Potassium chloride 2.4g, Sodium acetate (as trihydrate) 2.0g. **1440ml bag** Amino acids and electrolytes (Vamin 18 Novum) 300ml, Glucose (Glucose 11%) 885ml, Fat emulsion (Intralipid 20%) 255ml – corresponding to: Purified soybean oil 51g, Glucose (anhydrous) 97g, Alanine 4.8g, Arginine 3.4g, Aspartic acid 1.0g, Glutamic acid 1.7g, Glycine 2.4g, Histidine 2.0g, Isoleucine 1.7g, Leucine 2.4g, Lysine 2.7g, Methionine 1.7g, Phenylalanine 2.4g, Proline 2.0g, Serine 1.4g, Threonine 1.7g, Tryptophan 0.57g, Tyrosine 0.069g, Valine 2.2g, Calcium chloride (as dihydrate) 0.22g, Sodium glycerophosphate (hydrated) 1.5g, Magnesium sulphate (as heptahydrate) 0.48g, Potassium chloride 1.8g, Sodium acetate (as trihydrate) 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:** Intravenous infusion into a peripheral or central vein. The dose should be individualised to the patient's clinical condition, body weight and nutritional requirements. To minimise the risk of thrombophlebitis when used peripherally, daily rotation of infusion site is recommended. Recommended maximum daily dose – 40ml/kg body weight (bw)/day. Maximum infusion rate – 3.7ml/kg bw/hour (corresponding to 0.25g glucose, 0.09g amino acids and 0.13g fat/kg bw). The recommended infusion period per bag is 12-24 hours. For children aged 2-10 years, start with a low dose 14-28ml/kg and increase by 10-15ml/kg/day to a maximum of 40ml/kg/day. For children over 10 years the adult dosage can be applied. The addition of trace elements and vitamins is always required. Supplemental electrolytes may be required. **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 hemofiltration or dialysis, acute shock, hyperglycaemia that requires more than 6 units insulin/h, pathologically elevated serum levels of any of the included electrolytes, general contraindications to infusion therapy, haemophagocytotic syndrome, unstable conditions, infants and children 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 towards electrolyte retention, in metabolic acidosis (e.g. lactic acidosis), increased serum osmolarity or those in need of fluid resuscitation. The bag size should be carefully chosen and volumes adjusted according to hydration and nutritional status. Contains soya-bean oil and egg phospholipids which may rarely cause allergic reactions. Cross allergic reaction has been observed 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 occur, the infusion must be stopped. Regularly monitor serum glucose, electrolytes, osmolarity, fluid balance, acid-base status and liver enzyme tests. When fat is given for a longer period, monitor blood cell count and coagulation. Thrombophlebitis may occur if peripheral veins are used. Other precautions may be necessary – see SmPC for details. **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 reactions, hypotension, hypertension, tachypnoea, priapism. Other adverse reactions can occur (including fat overload syndrome), see SmPC for details. **Legal Category:** POM **Marketing Authorisation Holder:** Fresenius Kabi Limited, Cestrian Court, Eastgate Way, Manor Park, Runcorn, Cheshire, WA7 1NT, UK. **Marketing Authorisation Number:** PL 08828/0148. **Package size and cost:** 2400ml £55.72, 1920ml £44.09, 1440ml £30.77. **Further information:** See the SmPC for further details. **Adverse events should be reported.** Reporting forms and information can be found at **https://yellowcard.mhra.gov.uk.** Adverse events should also be reported to Fresenius Kabi Limited. **Date of preparation:** April 2019.

Addaven® Concentrate for Solution for Infusion (chromium, copper, iron, manganese, iodine, fluoride, molybdenum, selenium, zinc)

ABBREVIATED PRESCRIBING INFORMATION – Addaven® concentrate for solution for infusion. Active Ingredients: One ampoule of 10ml Addaven contains: Chromic chloride hexahydrate 53.3 microgram, Copper chloride dihydrate 1.02 milligram, Ferric chloride hexahydrate 5.40 milligram, Manganese chloride tetrahydrate 198 microgram, Potassium iodide 166 microgram, Sodium fluoride 2.10 milligram, Sodium molybdate dihydrate 48.5 microgram, Sodium selenite 173 microgram, Zinc chloride 10.5 milligram. **Indications:** To meet basal to moderately increased requirements of trace elements in intravenous nutrition. **Dosage and administration:** Addaven must not be given undiluted. Recommended daily dosage in adults with basal to moderately increased requirements is 10ml (one ampoule). Addaven is not recommended for use in children under 40kg of body weight. For children weighing less than 40kg, the trace element solution Peditrace® should be used. **Contraindications:** Hypersensitivity to the active substances or excipients. **Special warnings and precautions for use:** Caution in patients with impaired biliary and/or renal function due to a decrease in excretion, which may lead to accumulation. Caution in patients with biochemical or clinical evidence of liver dysfunction (especially cholestasis). If the treatment exceeds 4 weeks, checking of manganese levels in blood is required. Individual requirements of trace elements should be considered and separate supplementation may be required. **Undesirable effects:** None known. **Legal Category:** POM. **Marketing Authorisation Holder:** Fresenius Kabi Ltd, Cestrian Court, Eastgate Way, Manor Park, Runcorn, Cheshire WA7 1NT, UK **Marketing Authorisation Number:** PL 08828/0275. **Package size and cost:** 20 x 10ml ampoules £55 **Further information:** See SmPC for details. **Adverse events should be reported.** Reporting forms and information can be found at https://yellowcard.mhra.gov.uk. Adverse events should also be reported to Fresenius Kabi Limited. **Date of revision:** May 2019.

Solivito® N Powder for Concentrate for Solution for Infusion (thiamine, riboflavine, nicotinamide, pyridoxine, sodium pantothenate, sodium ascorbate, biotin, folic acid, cyanocobalamin)

SOLIVITO® N POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION. Active Ingredients: 2566ml bag Thiamine Mononitrate 3.1mg, Sodium Riboflavine Phosphate 4.9mg, Nicotinamide 40mg, Pyridoxine Hydrochloride 4.9mg, Sodium Pantothenate 16.5mg, Sodium Ascorbate 113mg, Biotin 60µg, Folic acid 0.4mg, Cyanocobalamin 5µg. Excipients with known effect: methyl parahydroxybenzoate 0.5mg per vial. **Indications**: A supplement in intravenous nutrition to provide the daily requirements of water-soluble vitamins in adults and children. **Dosage and administration**: For intravenous infusion after dilution in a compatible solution (refer to SmPC). One vial should be infused over a minimum of two to three hours in patients with normal renal function. All additions should be made aseptically. Adults and children 10kg or more: one vial daily. Solivito N may be added to parenteral nutrition admixtures provided compatibility and stability have been confirmed. Infants and children under 10kg: 1/10 the contents of one vial per kg body weight/day. **Contraindications**: Hypersensitivity to any of the active substances or excipients. **Precautions for use**: Biotin may interfere with laboratory tests that are based on a biotin/streptavidin interaction, leading to either falsely decreased or falsely increased test results, depending on the assay. Possible biotin interference has to be taken into consideration when interpreting results of laboratory tests, especially if a lack of coherence with the clinical presentation is observed. Laboratory personnel should be consulted when ordering laboratory tests in patients taking biotin. Interactions: Pyridoxine (Vitamin B6) can reduce the effect of levodopa. Some of the optic neuropathies appear to respond to massive doses of hydroxocobalamin and have been claimed to be adversely affected by administration of cyanocobalamin. Folic acid may lower the serum concentration of phenytoin and obscure pernicious anaemia. **Undesirable effects**: Anaphylactic reaction (risk level cannot be estimated from the available data). Other adverse reactions can occur, see SmPC for details. **Legal category**: POM. **Marketing authorisation number**: PL 08828/0116. **Marketing Authorisation Holder**: Fresenius Kabi Limited, Cestrian Court, Eastgate Way, Manor Park, Runcorn, Cheshire, WA7 1NT, UK. **Package size and cost**: 10 vials - £19.70. **Further information**: Prescribers should consult the summary of product characteristics in relation to other **adverse reactions**. Reporting forms and information can be found at **https://yellowcard.mhra.gov.uk**. Adverse events should also be reported to Fresenius Kabi Limited. **Date of preparation**: May 2020

Vitlipid® N Adult Concentrate for Emulsion for Infusion (ergocalciferol, phytomenadione, retinol palmitate, dl-alpha-tocopherol)

ABBREVIATED PRESCRIBING INFORMATION – VITLIPID® N ADULT concentrate for emulsion for infusion. Active ingredients: In 10ml - Retinol Palmitate corresponding to retinol 990mcg (3,300IU), Ergocalciferol 5mcg (200IU), dl-alpha-tocopherol 9.1mg (10 IU), Phytomenadione 150mcg. **Indications:** In adults and children from 11 years of age as a supplement in intravenous nutrition in order to meet the daily requirements of the fat-soluble vitamins A1, D2, E and K1. **Dosage and administration:** Recommended daily dosage for adults, the elderly and children over 11 years of age: One ampoule (10ml) Vitlipid N Adult is added to 500ml of Intralipid 10% or 20%. **Contraindications:** Hypersensitivity to egg, soya, or peanut protein or to any of the active substances or excipients. **Special warnings and precautions for use:** Contains soya-bean oil and egg phospholipids which may rarely cause allergic reaction. Cross allergic reaction has been observed between soya-bean and peanut. Must not be administered undiluted. The addition of the formulation to infusion solutions should be made aseptically and the solution used within 24 hours of preparation. **Undesirable effects:** None reported. Adverse reactions can occur, see SmPC for details. **Legal category:** POM. **Marketing Authorisation Holder:** Fresenius Kabi Limited, Cestrian Court, Eastgate Way, Manor Park, Runcorn, Cheshire WA7 1NT, UK. **Marketing authorisation number:** PL 8828/0124. **Package size and cost:** 10 x 10ml - £19.70. **Further information:** See the SmPC for further details. **Adverse events should be reported.** Reporting forms and information can be found at **https://yellowcard.mhra.gov.uk.** Adverse events should also be reported to Fresenius Kabi Limited. **Date of revision:** June 2021.

SMOFlipid® 200mg/ml Emulsion for Infusion (soya-bean oil, medium-chain triglycerides, olive oil and fish oil)

SMOFLIPID EMULSION FOR INFUSION Active Ingredients: 2566ml bag 1000ml contains: Soya-bean oil (refined) 60g, Medium-chain triglycerides 60g, Olive oil (refined) 50g, Fish oil (rich in omega-3-acids) 30g. 1000ml emulsion contains up to 5 mmol sodium. **Indications**: Supply of energy and essential fatty acids and omega-3 fatty acids to patients, as part of a parenteral nutrition regimen, when oral or enteral nutrition is impossible, insufficient or contraindicated. **Dosage and administration**: Intravenous infusion into a peripheral or central vein. The dosage and infusion rate should be governed by the patient's ability to eliminate fat. Adults – standard dose is 1.0–2.0g fat/kg body weight (bw)/day (5–10 ml/kg bw/day). Recommended infusion rate is 0.125g fat/kg bw/hour and should not exceed 0.15g fat/kg bw/hour, corresponding to 0.75ml SMOFlipid/kg bw/hour. Children – infusion rate should not exceed 0.15g fat/kg bw/hour. Increase daily dose gradually over the first week of administration. The maximum recommended daily dose is 3g fat/kg bw/day, corresponding to 15ml SMOFlipid/kg bw/day. Neonates and infants – initial dose should be 0.5–1.0g fat/kg bw/day followed by a successive increase of 0.5–1.0g fat/kg/bw/day up to 3.0g fat/kg bw/day (corresponding to 15ml SMOFlipid/kg bw/day). The infusion rate should not exceed 0.125g fat/kg bw/hour. In premature and low birthweight neonates, infuse SMOFlipid continuously over about 24 hours. Administer as part of a complete parenteral nutrition treatment including amino acids and glucose. When used in neonates and children below 2 years, the solution (in bags and administration sets) should be protected from light exposure until administration is completed. **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, severe renal insufficiency without access to hemofiltration or dialysis, acute shock, general contraindications to infusion therapy, unstable conditions (see SmPC). **Special warnings and precautions for use**: Monitor individual's capacity to eliminate fat. Dose reduction or cessation of infusion should be considered if serum or plasma triglyceride concentrations during or after infusion exceed 3mmol/L. Use with caution in conditions of impaired lipid metabolism, in patients with marked risk for hyperlipidemia, in neonates and premature neonates with hyperbilirubinemia and/or pulmonary hypertension. Light exposure of solutions for intravenous parenteral nutrition, especially after admixture with trace elements and/or vitamins, may have adverse effects on clinical outcome in neonates, due to generation of peroxides and other degradation products. 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. Administration of medium-chain fatty acids alone can result in metabolic acidosis; simultaneous infusion of carbohydrate or a carbohydrate-containing amino acid solution is recommended. Laboratory tests generally associated with monitoring of intravenous nutrition should be checked regularly. Monitor blood platelet counts, liver function tests and serum triglycerides in neonates. Any sign or symptom of anaphylactic reaction should lead to immediate interruption of the infusion. High plasma lipid levels may interfere with some laboratory blood tests. **Undesirable effects**: Common – slight increase in body temperature. Uncommon – lack of appetite, nausea, vomiting, chills. Rare – hypotension, hypertension, dyspnoea, hypersensitivity reactions, heat or cold sensation, paleness, cyanosis, pain in the neck, back, bones, chest and loins. Very rare – priapism. Other adverse reactions can occur (including fat overload syndrome), see SmPC for details. **Legal Category**: POM. **Marketing Authorisation Number**: PL 08828/0166. **Marketing Authorisation Holder**: Fresenius Kabi Limited, Cestrian Court, Eastgate Way, Manor Park, Runcorn, Cheshire WA7 1NT, UK. **Package Size and Cost**: UK: 100ml £7.44, 250ml £11.90, 500ml - £17.43. **Further information**: Prescribers should consult the summary of product characteristics in relation to other **adverse reactions. Adverse events should be reported** at **https://yellowcard.mhra.gov.uk** and to Fresenius Kabi Limited. **Date of Preparation**: June 2020

Aminoven® 16 Solution for Infusion (amino acids 10%)

AMINOVEN 16 SOLUTION FOR INFUSION Active Ingredients: 1000ml contains: Isoleucine 5g, Leucine 7.4g, Lysine 6.6g, Methionine 4.3g, Phenylalanine 5. lg, Threonine 4.4g, Tryptophan 2g, Valine 6.2g, Arginine 12g, Histidine 3g, Alanine 14g, Glycine llg, Praline 11.2g, Serine 6.5g, Tyrosine 0.4g, Taurine lg. **Indications**: For the supply of amino acids as part of a parenteral nutrition regimen. **Dosage and administration**: For administration via a central vein as a continuous infusion. The dosage of amino acids depends on the body weight and clinical condition of the patient. The recommended infusion period is 14-24 hours. Adult dosage: 10-20ml/kg body weight/day. Maximum infusion rate: lml/kg body weight/hour. Children and adolescent dosage (2-18 years): Maximum infusion rate and maximum daily dosage are the same as for adults. Dosage should be adjusted to hydration status, biological development and body weight. **Contraindications**: Should not be used in children under 2 years, in disturbances of amino acid metabolism, metabolic acidosis, renal insufficiency without haemodialysis or haemofiltration, advanced liver insufficiency, fluid overload, shock, hypoxia, decompensated heart failure. **Special warnings and precautions for use**: Monitor serum electrolytes, fluid balance and renal function. In cases of hypokalemia and/or hyponatremia adequate amounts of potassium and/or sodium should be supplied. Amino acid solutions may precipitate acute folate deficiency; folic acid should be given daily. Standard precautions for infusion therapy should be taken. Use as part of total parenteral nutrition in combination with adequate amounts of energy, electrolytes, vitamins and trace elements. **Undesirable effects**: None known when correctly administered. Infusion via peripheral veins in general can cause thrombophlebitis. Other adverse reactions can occur, see SmPC for details. **Legal Category**: POM. **Marketing Authorisation Holder**: Fresenius Kabi Ltd, Cestrian Court, Eastgate Way, Manor Park, Runcorn, Cheshire WA7 lNT, UK. **Marketing Authorisation Number**: PL 08828/0128 **Package size and cost**: 500ml - £17.00, 1000ml - £26.00 **Further information**: See SmPC for further details. **Adverse events should be reported**. Reporting forms and information can be found at **https:/ /yellowcard.mhra.gov.uk**. Adverse events should also be reported to Fresenius Kabi Limited. **Date of preparation**: November 2017.

Intralipid® 20% Emulsion for Infusion (soya-bean oil)

INTRALIPID® 20% EMULSION FOR INFUSION. Active Ingredients: Purified Soybean Oil Ph. Eur 20% w/v Indications: For use as part of a balanced intravenous feeding regimen in patients who are unable to receive sufficient amounts of nutrients enterally. Intralipid is especially valuable in providing a high energy intake to compensate for increased energy expenditure following trauma, infections and severe burns. **Dosage and administration**: Slow intravenous infusion. During first 10 minutes drip should be adjusted to 20 drops per minute then after half an hour of 25-40 drops per minute gradually increased to final rate. 500ml Intralipid 20% should be given over at least five hours. On first day of infusion advisable to administer 5ml/kg bodyweight (bw). Dosage may be increased to a maximum of 3g fat/kg bw/24 hours. Can be given as a separate infusion or as part of an admixture (approved for physical stability). Dosage and infusion rate should be governed by the patient's ability to utilise fat and in line with the following ranges. Adults - 500- 1000 ml per 24 hours in conjunction with amino acid and carbohydrate solutions. Essential fatty acid deficiency (EFAD) - 4-8% non-protein calories supplied as Intralipid for prevention or correction; substantially increase dose if EFAD associated with stress. Elderly - Caution in the 'frail' elderly and in all patients with poor renal, cardiac or liver function where smaller volumes should be used. Infants - Dosage is governed by the maturity and birth weight of the infant. Check daily infant's ability to eliminate infused fat through measurement of serum triglycerides. If lipaemia present retest after 4 hours. If possible, infuse continuously over 24 hours and use an appropriate pump to maintain constant infusion rate. Mature infants - 0.5-4.0 g fat/kg bw/24 hours (0.10-0.85 ml/kg/hour). Gradually increase dosage over the first week of administration. Premature and low birth weight infants: - Continuous infusion over 24 hours/day. Initially 0.5-1.0 g/kg/24 hours increasing by the same amount every 24 hours up to 2.0 g/kg/24 hours. Only increase to a maximum of 4g/kg/24 hours by careful monitoring of triglyceride levels, liver function tests and oxygen saturation. When used in neonates and children below 2 years, the solution (in bags and administration sets) should be protected from light exposure until administration is completed. Correct electrolyte, fluid, acid-base imbalance and shock prior to starting intravenous nutrition. In the seriously ill patient specific preliminary investigations and continuous monitoring are essential. Monitor vitamin and trace element levels especially in long-term intravenous nutrition. **Contraindications**: Hypersensitivity to egg, soya or peanut protein, or to any of the active substances or excipients, severe hyperlipidaemia, severe liver insufficiency, hemophagocytic syndrome, and in patients with acute shock. Special warnings and precautions for use: Use with caution in conditions of impaired lipid metabolism (check fat elimination daily), in newborns with neonatal hyperbilirubinaemia, and in infants with known or suspected pulmonary hypertension. Monitor platelet count, liver function tests and serum triglyceride concentration in neonates and particularly in prematures on long term parenteral nutrition. Contains soya-bean oil and egg phospholipids which may rarely cause allergic reactions. Cross allergic reaction has been observed between soybean and peanut. Closely monitor the elimination of fat in conditions of impaired lipid metabolism, and in patients given Intralipid for more than one week. Light exposure of solutions for intravenous parenteral nutrition, especially after admixture with trace elements and/or vitamins, may have adverse effects on clinical outcome in neonates, due to generation of peroxides and other degradation products. Intralipid may interfere with certain laboratory measurements if blood sampled before adequate fat clearance from bloodstream (see SmPC). **Undesirable effects**: In rare instances rise in temperature and less frequently shivering, chills and nausea/vomiting (discontinue Intralipid in such cases). Hypersensitivity reactions, respiratory symptoms, circulatory effects, haemolysis, reticulocytosis, abdominal pain, headache, tiredness and priapism have been reported. Other adverse reactions can occur (including fat overload syndrome), see SmPC for details. **Legal Category**: POM. **Marketing Authorisation Holder**: Fresenius Kabi Limited, Cestrian Court, Eastgate Way, Manor Park, Runcorn, Cheshire, WA7 lNT. **Marketing Authorisation Number**: PL 08828/0110. **Package size and cost**: l0xl0O ml £62.10, 10x250 ml £101.60, 12x500 ml £162.24. **Further information**: See SmPC for details. **Adverse events should be reported**. Reporting forms and information can be found at **https:/ /yellowcard.mhra.gov.uk**. Adverse events should also bereported to Fresenius Kabi Limited. **Date of revision**: February 2021.

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