Prescribing Information

Prescribing information available here, please scroll. For best viewing please use laptop/pc or similar sized screen.

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

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

Prescribing Information

Prescribing information available here, please scroll.

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

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

Prescribing Information

Prescribing information available here, please scroll.

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

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

Prescribing Information

Prescribing information available here, please scroll.

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

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

Prescribing Information

Prescribing information available here, please scroll.

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

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

Prescribing Information

Prescribing information available here, please scroll.

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

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

Prescribing Information

Prescribing information available here, please scroll.

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

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

Prescribing Information

Prescribing information available here, please scroll.

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

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

Prescribing Information

Prescribing information available here, please scroll.

SMOFlipid (soya-bean oil, medium-chain triglycerides, olive oil, fish oil) 200mg/ml emulsion for infusion

SMOFlipid 200mg/ml emulsion for infusion. Consult the Summary of Product Characteristics for full information. Additional information is available on request. **Active ingredients:** 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; should signs occur discontinue SMOFlipid), see SmPC for details. **Legal Category:** POM. **Marketing Authorisation Number:** UK - PL 08828/0166. IE – PA 2059/062/001 (Glass bottle), PA 2059/062/002 (Excel bag) **Marketing Authorisation Holder:** UK - Fresenius Kabi Limited, Cestrian Court, Eastgate Way, Manor Park, Runcorn, Cheshire WA7 1NT, UK. IE – Fresenius Kabi Deutschland GmbH, Else-Kroener Strasse 1, Bad Homburg v.d.h. 61352, Germany. **Package Size and Cost: UK:** 100ml £7.44, 250ml £11.90, 500ml - £17.43. **Further information:** Available from Fresenius Kabi Limited, Cestrian Court, Eastgate Way, Manor Park, Runcorn, Cheshire, WA7 1NT. Tel +44 (0)1928 533 533. **Date of preparation:** October 2020 API/SMOF-01

Prescribing Information

Prescribing information available here, please scroll.

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

PRESCRIBING INFORMATION – VITLIPID® N ADULT concentrate for emulsion for infusion. Consult the Summary of Product Characteristics for full information. Additional information is available on request. **Active ingredients:** 10 ml contains Retinol palmitate corresponding to retinol 990 micrograms (3,300 IU), Ergocalciferol 5 micrograms (200 IU), dl-alpha-tocopherol 9.1 mg (10 IU), Phytomenadione 150 micrograms. Indications: For use as a supplement in intravenous nutrition in adults and children (from 11 years of age) to meet the daily requirements of the fat soluble vitamins A1, D2, E and K1. **Dosage and administration:** For intravenous infusion after dilution (See SmPC). Recommended daily dosage for adults, the elderly and children (11 – 18 years): One ampoule (10ml) Vitlipid N Adult. **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. Do not administer undiluted. Addition of the formulation to infusion solutions should be made aseptically and the solution used within 24 hours of preparation. If the patient is pregnant or likely to become pregnant evaluate total daily dose of Vitamin A considering concomitant intake from food. **Undesirable effects:** No adverse effects related to Vitlipid N Adult have been reported. Adverse reactions can occur, see SmPC for details. **Legal category:** POM Marketing **Authorisation Holder:** IE: Fresenius Kabi Deutschland GmbH, Else-Kroener Strasse 1, Bad Homburg v.d.h. 61352, Germany. UK: Fresenius Kabi Ltd, Cestrian Court, Eastgate Way, Manor Park, Runcorn, Cheshire WA7 1NT. UK. **Marketing authorisation number:** IE: PA 2059/067/001. UK: PL 8828/0124. **Package size and cost:** 10 x 10ml - £19.70 **Further information:** Available from Fresenius Kabi Limited, Cestrian Court, Eastgate Way, Manor Park, Runcorn, Cheshire, WA7 1NT. Tel +44 (0)1928 533 533 **Date of preparation:** September 2023, IE-VitIp-2300001

Prescribing Information

Prescribing information available here, please scroll.

Solivito® N (thiamine, riboflavine, nicotinamide, pyridoxine, sodium pantothenate, sodium ascorbate, biotin, folic acid, cyanocobalamin) Powder for Concentrate for Solution for Infusion is marketed in the UK and ROI; please see prescribing information specific to your region.

For ROI Healthcare Professionals only.

SOLIVITO® N powder for concentrate for solution for infusion. Consult the Summary of Product Characteristics for full information. Additional information is available on request. **Active ingredients:** One 10 ml vial contains Thiamine nitrate 3.1 mg, Riboflavine Sodium Phosphate 4.9 mg, Nicotinamide 40 mg, Pyridoxine Hydrochloride 4.9 mg, Sodium Pantothenate 16.5 mg, Sodium Ascorbate 113 mg, Biotin 60 micrograms, Folic acid 0.4 mg, Cyanocobalamin 5 micrograms. Excipients: 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. ***Adults, elderly and children 10kg or more:*** one vial daily. ***Infants and children under 10kg:*** 1/10 the contents of one vial per kg body weight/day. Solivito N may be added to parenteral admixtures containing carbohydrates, lipids, amino acids, electrolytes and trace elements provided that compatibility and stability have been confirmed. **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. Care in the administration of cyanocobalamin with some of the optic neuropathies. If Solivito N is diluted with water based solutions the admixture should be protected from light. Folic acid may obscure pernicious anaemia. Methyl parahydroxybenzoate may cause allergic reactions (possibly delayed), including bronchospasm. **Interactions:** Pyridoxine (Vitamin B6) can reduce the effect of levodopa. Folic acid may lower the serum concentration of phenytoin. **Undesirable effects:** Allergic reactions, 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:** PA 2059/064/001. **Marketing Authorisation Holder:** Fresenius Kabi Deutschland GmbH, Else-Kroener Straβe 1, Bad Homburg 61352, v.d.Höhe, Germany. **Further information:** Available from Fresenius Kabi Limited, Cestrian Court, Eastgate Way, Manor Park, Runcorn, Cheshire, WA7 1NT. Tel +44 (0)1928 533 533 **Date of preparation:** November 2020 API/Solivito-01

For UK Healthcare Professionals only.

SOLIVITO® N powder for concentrate for solution for infusion. Active ingredients: 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

Prescribing Information

Prescribing information available here, please scroll.

Additrace N® (chromium, copper, iron, manganese, iodine, fluoride, molybdenum, selenium, zinc) and Addaven® (chromium, copper, iron, manganese, iodine, fluoride, molybdenum, selenium, zinc) have the same composition, but are marketed under different names in the UK and ROI; please see prescribing information specific to your region.

For ROI Healthcare Professionals only.

Additrace® N Concentrate for solution for infusion. Consult the Summary of Product Characteristics for full information. Additional information is available on request. **Active ingredients:** Each 10ml ampoule of Additrace N 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 anhydrous 173 microgram, Zinc chloride 10.5 milligram. **Indications:** To meet basal to moderately increased requirements of trace elements in intravenous nutrition. **Dosage and administration:** Additrace N must not be given undiluted; only add to medicinal or nutritional solutions for which compatibility has been documented. Recommended daily dosage for adults with basal to moderately increased requirements: 1 ampoule (10ml). Additrace N is not recommended for use in children weighing under 40kg body weight; Peditrace® should be used. Dosage is dependent on age, weight and any degree of deficiency of the patient and must be decided on an individual basis. **Contraindications:** Hypersensitivity to the active substances or any of the excipients, conditions with total biliary obstruction, Wilson's disease. **Special warnings and precautions for use:** Use with caution in patients with impaired biliary and/or renal function in whom the excretion of trace elements (zinc, selenium, fluoride, chromium and molybdenum) may be significantly decreased, and in patients with biochemical or clinical evidence of liver dysfunction (especially cholestasis). Check manganese blood levels if treatment continued for more than 4 weeks. Stop Additrace N if manganese levels rise to the potentially toxic range (refer to appropriate reference ranges of the testing laboratory). Carefully monitor the unborn baby during intravenous administration of parenteral irons to pregnant women; foetal bradycardia can occur. **Undesirable effects:** No adverse effects related to the trace elements in Additrace N have been reported. Other adverse reactions can occur, see SmPC for details. **Legal Category:** POM **Marketing Authorisation Holder:** Fresenius Kabi Deutschland GmbH, Else-Kroener Strasse 1, Bad Homburg v.d.h. 61352, Germany. Marketing Authorisation Number: PA 2059/023/002 **Further information:** Available from Fresenius Kabi Limited, Cestrian Court, Eastgate Way, Manor Park, Runcorn, Cheshire, WA7 1NT. Tel +44 (0)1928 533 533. **Date of preparation:** December 2020 API/AdditraceN-01

For UK Healthcare Professionals only.

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.

Prescribing Information **Prescribing information available here, please scroll.**

IDACIO▼ (adalimumab) 40 mg

Consult the Summary of Product Characteristics for full information. Additional information is available on request.

IDACIO▼(adalimumab) 40 mg

▼This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. See below for how to report adversereactions.

IDACIO 40 mg solution for injection in pre-filled syringe.

IDACIO 40 mg solution for injection in pre-filled pen.

IDACIO 40 mg solution for injection in vial for paediatric use.

Presentation and method of administration: Each single dose 0.8 ml pre-filled syringe, 0.8 ml pre-filled pen or 0.8 ml vial contains 40 mg of adalimumab for subcutaneous injection. **Indications and Dosage:** Please refer to SmPC for full information. Idacio treatment should be initiated and supervised by specialist physicians experienced in the diagnosis and treatment of conditions for which Idacio is indicated. Ophthalmologists are advised to consult with an appropriate specialist before initiation of treatment with Idacio. Patients treated with Idacio should be given a patient alert card. After proper training in injection technique, patients may self-inject with Idacio if their physician determines that it is appropriate and with medical follow-up as necessary. During treatment with Idacio, other concomitant therapies (e.g., corticosteroids and/or immunomodulatory agents) should be optimised. **Rheumatoid arthritis (RA), adults:** In combination with methotrexate (MTX) for moderate to severe, active RA with inadequate response to disease-modifying anti-rheumatic drugs (DMARDs) including MTX. In combination with MTX for severe, active and progressive RA when not previously treated with MTX. Can be given as monotherapy if intolerance to or when continued treatment with MTX is inappropriate. Reduces rate of progression of joint damage on X-ray and improves physical function, in combination with MTX. Dosage:40 mg single dose every other week (EOW). Concomitant MTX should be continued. In monotherapy, patients may require 40 mg every week or 80 mg EOW if they experience decrease in clinical response. Treatment beyond 12 weeks should be reconsidered if no clinical response in that time. Consider need for dose interruption, e.g. before surgery or if serious infection occurs. Reintroduction after 70 days or longer of discontinuation gave same magnitudes of clinical response and similar safety profile as before dose interruption. **Polyarticular juvenile idiopathic arthritis (pJIA), paediatrics 2 years and above:** In combination with MTX for active pJIA with inadequate response to one or more DMARDs. Can be given as monotherapy if intolerance to or when continued treatment with MTX is inappropriate. Dosage: 10 kg to < 30 kg 20 mg single dose EOW. If 30 kg: 40 mg single dose EOW. Treatment beyond 12 weeks should be reconsidered if no clinical response in that time. **Enthesitis-related arthritis (ERA), paediatrics 6 years and above:** For active ERA with inadequate response to or intolerance to conventional therapy. Dosage: 15 kg to < 30 kg: 20 mg single dose EOW. If 30 kg: 40 mg single dose EOW. **Ankylosing spondylitis (AS), adults:** For severe active AS with inadequate response to conventional therapy. Dosage: adults: 40 mg single dose EOW. Treatment beyond 12 weeks should be reconsidered if no clinical response in that time. **Axial spondyloarthritis without radiographic evidence of AS (nr-axSpA), adults:** For severe nr-axSpA with objective signs of inflammation (elevated CRP and/or MRI), and an inadequate response to or intolerance to nonsteroidal anti-inflammatory drugs. Dosage: 40 mg single dose EOW. Treatment beyond 12 weeks should be reconsidered if no clinical response in that time. **Psoriatic arthritis (PsA), adults:** For active and progressive PsA with inadequate response to DMARDs. Reduces rate of progression of peripheral joint damage on X-ray in polyarticular symmetrical subtypes of the disease and improves physical function. Dosage: 40 mg single dose EOW. Treatment beyond 12 weeks should be reconsidered if no clinical responsecin that time. **Psoriasis, adults:** For moderate to severe chronic plaque psoriasis in candidates for systemic therapy. Dosage: 80 mg initial dose at Week 0, followed by 40 mg EOW from Week 1. Treatment beyond 16 weeks should be reconsidered if no clinical response in thatctime (refer to SmPC). **Paediatric Plaque Psoriasis,** 4 years and above: For severe chronic plaque psoriasis with inadequate response to or if topical therapy and phototherapies are inappropriate. Dosage: 15 kg to < 30 kg: 20 mg dose initially followed by 20 mg EOW starting one week after initial dose. If 30 kg: 40 mg dose initially followed by 40 mg EOW starting one week after initial dose. Treatment beyond 16 weeks should be reconsidered if no clinical response in that time. **Hidradenitis suppurativa (HS), adults and adolescents from 12 years and above: F**or active moderate to severe HS (acne inversa) with inadequate response to conventional systemic HS therapy. Dosage: HS, adults: 160 mg dose initially at Day 1, followed by 80 mg two weeks later at Day 15. Two weeks later (Day 29) continue with a dose of 40 mg every week or 80 mg EOW. HS, adolescents 12 years and above 30 kg: 80 mg initial dose at Week 0, followed by 40 mg EOW from Week 1. If there is inadequate response to 40 mg EOW, an increase in dosage to 40 mg every week or 80 mg EOW may be considered. Antibiotics may be continued if necessary. Concomitant topical antiseptic wash on HS lesions is recommended to be used on a daily basis. Treatment beyond 12 weeks should be reconsidered if no improvement in that time. Reintroduction of Idacio after treatment interruption as appropriate. Evaluate periodically the benefit and risk of continued long-term treatment. **Crohn's disease (CD), adults:** For moderately to severely active CD with no response despite a full and adequate course of, intolerance to or contraindication for a corticosteroid and/or an immunosuppressant therapy. Dosage: Induction: 80 mg dose at Week 0, followed by 40 mg at Week 2. For a more rapid response: 160 mg at Week 0, followed by 80 mg at Week 2; risk of adverse events higher during rapid induction. Maintenance: 40 mg dose EOW. During maintenance, corticosteroids may be tapered in accordance with clinical guidelines. If decrease in clinical response, can increase dosage to 40 mg every week or 80 mg EOW. Patients with no response by Week 4 may benefit from continued maintenance therapy to Week 12. Treatment beyond 12 weeks should be reconsidered if no clinical response in that time. **Paediatric Crohn's disease (CD), 6 years and above:** For moderately to severely active CD with inadequate response to, intolerance to or contraindication for conventional therapy including primary nutrition therapy and a corticosteroid and/or an immunomodulator. Dosage: < 40 kg: Induction: 40 mg dose at Week 0, followed by 20 mg at Week 2. For a more rapid response: 80 mg at Week 0, followed by 40 mg at Week 2; risk of adverse events higher during rapid induction. Maintenance: 20 mg dose EOW from Week 4. If insufficient response, consider an increase in dosing frequency to 20 mg every week. If 40 kg: Induction: 80 mg dose at Week 0, followed by 40 mg at Week 2. For a more rapid response: 160 mg dose at Week 0, followed by 80 mg at Week 2; risk of adverse events higher during rapid induction. Maintenance: 40 mg dose EOW from week 4. If insufficient response, consider an increase in dosage to 40 mg every week or 80 mg EOW. Treatment beyond 12 weeks should be reconsidered if no clinical response in that time. **Ulcerative colitis (UC), adults:** For moderately to severely active UC with inadequate response to, intolerance to or contraindication for conventional therapy including corticosteroids and 6-mercaptopurine (6-MP) or azathioprine (AZA). Dosage: Induction: 160 mg dose at Week 0, followed by 80 mg at Week 2. Maintenance: 40 mg dose EOW. During maintenance, corticosteroids may be tapered in accordance with clinical guidelines. If insufficient response, consider an increase in dosage to 40 mg every week or 80 mg EOW. Treatment beyond 8 weeks should not be continued if no clinical response in that time. **Paediatric ulcerative colitis, 6 years and above:** For moderately to severely active UC with inadequate response to, intolerant to or contraindication for conventional therapy including corticosteroids and/or 6-mercaptopurine (6-MP) or azathioprine (AZA). Dosage: < 40 kg: Induction 80 mg at Week 0 (as two 40 mg injections in one day), followed by 40 mg at Week 2 (single injection). Maintenance: 40 mg EOW from Week 4. If 40 kg: Induction 160 mg at Week 0 (Either as four x 40 mg injections in one day or two x 40 mg injections across two consecutive days) followed by 80 mg at Week 2 (as two 40 mg injections in one day). Maintenance: 80 mg EOW from Week 4. Treatment beyond 8 weeks should be carefully considered if no clinical response in that time. Idacio patients who turn 18 years of age should continue their prescribed maintenance dose. **Uveitis, adults:** For non-infectious intermediate, posterior and panuveitis with inadequate response to corticosteroids, in patients in need of corticosteroid-sparing, or in whom corticosteroid treatment is inappropriate. Dosage: 80 mg initial dose at Week 0, followed by 40

mg EOW from Week 1. Treatment can be initiated in combination with corticosteroids and/or with other non-biologic immunomodulatory agents. Concomitant corticosteroids may be tapered in accordance with clinical practice starting two weeks after initiating treatment with Idacio. Evaluate on a yearly basis the benefit and risk of continued long-term treatment. **Paediatric Uveitis, 2 years and above:** For chronic non-infectious anterior uveitis with inadequate response to or intolerance to conventional therapy, or in whom conventional therapy is inappropriate. Dosage: < 30 kg: 20 mg dose EOW in combination with MTX. Optional 40 mg (for patients < 30 kg) or 80 mg (for patients 30 kg) loading dose one week prior to start of maintenance therapy. No clinical data in use of loading dose < 6 years of age (see SmPC). If 30 kg: 40 mg dose EOW in combination with MTX. Evaluate on a yearly basis the benefit and risk of continued long-term treatment. Idacio may be available in other strengths and/or presentations depending on the individual treatment needs. **Contraindications:** Hypersensitivity to the active substance or to any excipients (see SmPC); Active tuberculosis (TB) or other severe infections such as sepsis and opportunistic infections; Moderate to severe heart failure (NYHA class III/IV). **Warnings and precautions:** Clearly record the name and batch number of administered product to improve traceability of biological products. **Infections:** Patients taking TNF-antagonists are more susceptible to serious infections. Impaired lung function may increase the risk for developing infections. Monitor for infections, including TB, before, during and for at least 4 months after treatment. Treatment with Idacio should not be initiated in patients with active infections including chronic or localised infections until infections are controlled. In patients who have been exposed to tuberculosis and patients who have travelled in areas of high risk of tuberculosis or endemic mycoses, such as histoplasmosis, coccidioidomycosis, or blastomycosis, the risk and benefits of treatment with Idacio should be considered prior to initiating therapy. Evaluate new infections during treatment and monitor closely. Stop treatment if new serious infection or sepsis and treat appropriately. Exercise caution in patients with a history of recurring infections or who are predisposed to infections, including the use of concomitant immunosuppressive medications. **Serious infections:** Serious infections, including those associated with hospitalisation or death, were reported in patients receiving treatment. **TB: C**onsult SmPC for details. Reactivation and new onset TB, both pulmonary and extra-pulmonary (disseminated), were reported. Screen all patients before therapy initiation for active or inactive (latent) TB. Appropriate screening tests (i.e. tuberculin skin test and chest X-ray) should be performed in all patients. If latent TB is suspected, consult physician with appropriate expertise and follow local treatment recommendations for prophylaxis prior to initiation of Idacio. Despite prophylaxis, TB reactivation has occurred on adalimumab. If active TB is diagnosed, do not initiate Idacio treatment. **Other opportunistic infections:** Opportunistic infections were observed in patients receiving adalimumab. Stop treatment in patients with signs and symptoms of such infections. Consult with physician with appropriate expertise for diagnosis and administration of empiric antifungal therapy in these patients. **Hepatitis B reactivation:** Reactivation of HBV has occurred in chronic carriers (surface antigen positive). Patients should be tested for HBV infection before initiating treatment. HBV carriers should consult a specialist physician and be closely monitored for reactivation of HBV infection throughout therapy and for several months following termination of treatment. If reactivation occurs, stop treatment and initiate appropriate antiviral and supportive treatment. **Neurological events:** Caution in patients with pre-existing or recent-onset central or peripheral nervous system demyelinating disorders. Discontinuation of treatment should be considered if any of these disorders develop. Neurologic evaluation should be performed in patients with non-infectious intermediate uveitis prior to initiation of treatment and regularly during treatment, to assess for pre-existing or developing central demyelinating disorders. **Allergic reactions:** Reports of serious allergic reactions including anaphylaxis received. For serious allergic or anaphylactic reaction, stop Idacio immediately and initiate appropriate therapy. **Malignancies and lymphoproliferative disorders:** A possible risk has been reported of malignancy, including lymphomas and leukaemia, in all patients, including paediatric patients, treated with Tumour Necrosis Factor (TNF) antagonists. Examine all patients, especially those with a medical history of extensive immunosuppressant or PUVA treatment, for non-melanoma skin cancer prior to and during treatment; caution in COPD patients, and in patients with increased risk for malignancy due to heavy smoking. Consider the potential risk with the combination of azathioprine or 6-mercaptopurine and adalimumab (hepatosplenic T-cell lymphoma has occured). Risk of hepatosplenic T-cell lymphoma cannot be excluded. Caution in patients with a history of malignancy. Risk of developing dysplasia or colon cancer is unknown. Patients with UC with increased risk of dysplasia or colon carcinoma, or history of dysplasia or colon carcinoma, to be screened for dysplasia before treatment and throughout disease course. **Haematological reactions:** Adverse events of the haematological system reported with adalimumab. Patients should seek immediate medical attention if signs and symptoms of blood dyscrasias develop while on treatment. **Vaccinations:** Patients may receive concurrent vaccinations, except for live vaccines. Bring paediatric patients up to date with all immunisations prior to initiating Idacio treatment. **Congestive heart failure:** See contraindications. Caution is advised with mild heart failure (NYHA class I/II). Discontinue treatment if new or worsening symptoms of congestive heart failure. **Autoimmune processes:** Autoimmune antibodies may form with Idacio. Stop treatment if development of a lupus-like syndrome with positive antibodies against double-stranded DNA. **Surgery: C**onsider the long half-life of Idacio for planned surgical procedures. Monitor closely for infections. Elderly patients: Serious infections were higher in patients over 65 years of age, some of which had a fatal outcome. Consider risk of infections in these patients. **Interactions:** Antibody formation was lower when adalimumab was given together with MTX in comparison with use as monotherapy. Combination of Idacio with other biologic DMARDs (e.g. anakinra and abatacept) or other TNF-antagonists is not recommended. **Fertility, pregnancy and lactation:** Idacio should only be used during pregnancy if clearly needed. Women of childbearing age should consider the use of adequate contraception and continue its use for at least 5 months after the last treatment. No administration of live vaccines (e.g. BCG) to infants exposed to Idacio in utero for 5 months following mother's last Idacio treatment during pregnancy. Idacio can be used during breast-feeding. **Adverse Reactions:** Very common 1/10: Respiratory tract infections (including lower and upper respiratory tract infection, pneumonia, sinusitis, pharyngitis, nasopharyngitis and pneumonia herpes viral), leukopenia (including neutropenia and agranulocytosis), anaemia, lipids increased, headache, abdominal pain, nausea and vomiting, elevated liver enzymes, rash (including exfoliative rash), musculoskeletal pain, injection site reaction (including injection site erythema). Common 1/100 to < 1/10: Systemic infections (including sepsis, candidiasis and influenza), intestinal infections (including gastroenteritis viral), skin and soft tissue infections (including paronychia, celulitis, impetigo, necrotising fasciitis and herpes zoster), ear infections, oral infections (including herpes simplex, oral herpes and tooth infections), reproductive tract infections (including vulvovaginal mycotic infection), urinary tract infections (including pyelonephritis), fungal infections, joint infections, skin cancer excluding melanoma (including basal cell carcinoma and squamous cell carcinoma), benign neoplasm, leucocytosis, thrombocytopenia, hypersensitivity, allergies (including seasonal allergy), hypokalaemia, uric acid increased, blood sodium abnormal, hypocalcaemia, hyperglycaemia, hypophosphatemia, dehydration, mood alterations (including depression), anxiety, insomnia, paraesthesias (including hypoesthesia), migraine, nerve root compression, visual impairment, conjunctivitis, blepharitis, eye swelling, vertigo, tachycardia, hypertension, flushing, haematoma, asthma, dyspnoea, cough, GI haemorrhage, dyspepsia, gastroesophageal reflux disease, sicca syndrome, worsening or new onset of psoriasis (including palmoplantar pustular psoriasis), urticaria, bruising (including purpura), dermatitis (including eczema), onychoclasis, hyperhidrosis, alopecia, pruritus, muscle spasms (including blood creatine phosphokinase increased), renal impairment, haematuria, chest pain, oedema, pyrexia, coagulation and bleeding disorders (including activated partial thromboplastin time prolonged), autoantibody test positive (including double stranded DNA antibody), blood lactate dehydrogenase increased, impaired healing. Serious, including fatal, adverse reactions have been reported including infections/sepsis, TB, opportunistic infections, allergic reactions (including anaphylaxis), HBV reactivation and malignancies (including leukaemia, lymphoma and hepatosplenic T-cell lymphoma). Serious haematological, neurological and autoimmune reactions have also been reported. These include rare reports of pancytopenia, aplastic anaemia, central and peripheral demyelinating events and reports of lupus, lupus-related conditions and Stevens-Johnson syndrome. Other less common and rarely reported adverse reactions are listed in the SmPC. **Package size and cost:** UK / ROI, IDACIO 40mg/0.8ml vial x 1: £316.93 / €309.31, IDACIO 40mg/0.8ml pre-filled syringe x 2: £633.86 / €618.63, IDACIO 40mg/0.8ml pre-filled pen x 2: £633.86 / €618.63. **Legal Category:** POM. **EU Marketing Authorisation Holder:** Fresenius Kabi, Deutschland GmbH, Else-Kröner-Straße 1, 61352 Bad Homburg v.d.Höhe, Germany. **EU marketing authorisation numbers:** EU/1/19/1356/001, EU/1/19/1356/002, EU/1/19/1356/003. **GB Marketing Authorisation Holder:** Fresenius Kabi Ltd, Cestrian Court, Eastgate Way, Manor Park, Runcorn, Cheshire, WA7 1NT, United Kingdom. **GB marketing authorisation numbers:** PLGB 08828/0320, PLGB 08828/0321, PLGB 08828/0322. **Further information:** available from Fresenius Kabi Ltd., Cestrian Court, Eastgate Way, Manor Park, Runcorn, Cheshire, WA7 1NT. Tel *44 (0)1928 533 533. Fresenius Kabi Ltd., Unit 3B, Fingal Bay Business Park, Balbriggan, Co. Dublin, K32 X065 Ireland T: *353 (0) 1 841 3030. **Date of preparation of PI:** December 2021 IE-IDA-2100002

Adverse events should be reported.
Reporting forms and information can be found at:
yellowcard.mhra.gov.uk
www.hpra.ie/homepage/about-us/report-an-issue
Adverse events should also be reported to Fresenius Kabi Limited, Cestrian Court, Eastgate Way, Manor Park, Runcorn, Cheshire, WA7 1NT
Tel +44 (0)1928 533 533.

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