Prescribing information

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

FRESENIUS KABI

Prescribing information

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

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