Prescribing information

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

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