Prescribing information

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

FRESENIUS KABI

Prescribing information

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

Date of preparation: November 2023; IE-3CB-2300009

FRESENIUS KABI