

Prescribing information available here for the Fresenius Kabi parenteral nutrition macronutrient products, please scroll.

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

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), see SmPC for details. **Legal Category:** POM. **Marketing Authorisation Number:** PL 08828/0166. **Marketing Authorisation Holder:** Fresenius Kabi Limited, Cestrian Court, Eastgate Way, Manor Park, Runcorn, Cheshire WA7 1NT, UK. **Package Size and Cost:** UK: 100ml £7.44, 250ml £11.90, 500ml - £17.43. **Further information:** Prescribers should consult the summary of product characteristics in relation to other adverse reactions. Adverse events should be reported at <https://yellowcard.mhra.gov.uk> and to Fresenius Kabi Limited. **Date of Preparation:** June 2020

Aminoven® 8 solution for infusion (amino acids 5%)

Active Ingredients: 1000ml contains Isoleucine 2.5g, Leucine 3.7g, Lysine 3.3g, Methionine 2.15g, Phenylalanine 2.55g, Threonine 2.2g, Tryptophan 1g, Valine 3.1g, Arginine 6g, Histidine 1.5g, Alanine 7g, Glycine 5.5g, Proline 5.6g, Serine 3.25g, Tyrosine 0.2g, Taurine 0.5g. **Indications:** For the supply of amino acids as part of a parenteral nutrition regimen. **Dosage and administration:** For administration via a peripheral or central vein as a continuous infusion. The dosage of amino acids depends on the body weight and clinical condition of the patient. The recommended infusion period is 14-24 hours. Adult dosage: 16-20ml/ kg body weight/day. Maximum infusion rate 2ml/kg body weight/hour. Children and adolescent dosage (2-18 years): Maximum infusion rate 2ml/ kg body weight/hour. Dosage in children should be adjusted to hydration status, biological development and body weight, to a maximum of 40ml/ kg body weight/day. **Contraindications:** Should not be used in children under 2 years, in disturbances of amino acid metabolism, metabolic acidosis, renal insufficiency without haemodialysis or haemofiltration, advanced liver insufficiency, fluid overload, shock, hypoxia, decompensated heart failure. **Special warnings and precautions for use:** Monitor serum electrolytes, fluid balance and renal function. In cases of hypokalemia and/ or hyponatremia adequate amounts of potassium and/ or sodium should be supplied. Amino acid solutions may precipitate acute folate deficiency; folic acid should be given daily. Standard precautions for infusion therapy should be taken. Use as part of total parenteral nutrition in combination with adequate amounts of energy, electrolytes, vitamins and trace elements. **Undesirable effects:**

None known when correctly administered. Infusion via peripheral veins in general can cause thrombophlebitis. Other adverse reactions can occur, see SmPC for details. **Legal Category:** POM. **Marketing Authorisation Holder:** Fresenius Kabi Ltd, Cestrian Court, Eastgate Way, Manor Park, Runcorn, Cheshire WA7 1NT, UK. **Marketing Authorisation Number:** PL 08828/0127 **Package size and cost:** 500ml - £10.00, 1000ml - £19.50 **Further information:** See SmPC for further details. **Adverse events should be reported.** Reporting forms and information can be found at <https://yellowcard.mhra.gov.uk>. Adverse events should also be reported to Fresenius Kabi Limited. **Date of preparation:** November 2017.

Aminoven® 16 solution for infusion (amino acids 10%)

Active Ingredients: 1000ml contains: Isoleucine 5g, Leucine 7.4g, Lysine 6.6g, Methionine 4.3g, Phenylalanine 5.1g, Threonine 4.4g, Tryptophan 2g, Valine 6.2g, Arginine 12g, Histidine 3g, Alanine 14g, Glycine 11g, Praline 11.2g, Serine 6.5g, Tyrosine 0.4g, Taurine 1g. **Indications:** For the supply of amino acids as part of a parenteral nutrition regimen. **Dosage and administration:** For administration via a central vein as a continuous infusion. The dosage of amino acids depends on the body weight and clinical condition of the patient. The recommended infusion period is 14-24 hours. Adult dosage: 10-20ml/kg body weight/day. Maximum infusion rate: 1ml/kg body weight/hour. Children and adolescent dosage (2-18 years): Maximum infusion rate and maximum daily dosage are the same as for adults. Dosage should be adjusted to hydration status, biological development and body weight. **Contraindications:** Should not be used in children under 2 years, in disturbances of amino acid metabolism, metabolic acidosis, renal insufficiency without haemodialysis or haemofiltration, advanced liver insufficiency, fluid overload, shock, hypoxia, decompensated heart failure. **Special warnings and precautions for use:** Monitor serum electrolytes, fluid balance and renal function. In cases of hypokalemia and/or hyponatremia adequate amounts of potassium and/ or sodium should be supplied. Amino acid solutions may precipitate acute folate deficiency; folic acid should be given daily. Standard precautions for infusion therapy should be taken. Use as part of total parenteral nutrition in combination with adequate amounts of energy, electrolytes, vitamins and trace elements. **Undesirable effects:** None known when correctly administered. Infusion via peripheral veins in general can cause thrombophlebitis. Other adverse reactions can occur, see SmPC for details. **Legal Category:** POM. **Marketing Authorisation Holder:** Fresenius Kabi Ltd, Cestrian Court, Eastgate Way, Manor Park, Runcorn, Cheshire WA7 1NT, UK. **Marketing Authorisation Number:** PL 08828/0128 **Package size and cost:** 500ml - £17.00, 1000ml - £26.00 **Further information:** See SmPC for further details. **Adverse events should be reported.** Reporting forms and information can be found at <https://yellowcard.mhra.gov.uk>. Adverse events should also be reported to Fresenius Kabi Limited. **Date of preparation:** November 2017.

Aminoven® 25 solution for infusion (amino acids 15%)

Active Ingredients: 1000ml contains Isoleucine 5.2g, Leucine 8.9g, Lysine acetate 15.66g (= Lysine 11.1g), Methionine 3.8g, Phenylalanine 5.5g, Threonine 8.6g, Tryptophan 1.6g, Valine 5.5g, Arginine 20g, Histidine 7.3g, Alanine 25g, Glycine 18.5g, Proline 17g, Serine 9.6g, Tyrosine 0.4g, Taurine 2g. **Indications:** For the supply of amino acids as part of a parenteral nutrition regimen. **Dosage and administration:** For administration via a central vein as a continuous infusion. The dosage of amino acids depends on the body weight and clinical condition of the patient. The recommended infusion period is 14-24 hours. Adult dosage: 6.7-13.3ml/kg body weight/day. Maximum infusion rate: 0.67ml/kg body weight/hour. **Contraindications:** Aminoven 25 administration is contraindicated in children, in disturbances of amino acid metabolism, metabolic acidosis, renal insufficiency without haemodialysis or haemofiltration, advanced liver insufficiency, fluid overload, shock, hypoxia, decompensated heart failure. **Special warnings and precautions for use:** Monitor serum electrolytes, fluid balance and renal function. In cases of hypokalemia and/or hyponatremia adequate amounts of potassium and/or sodium should be supplied simultaneously. Amino acid solutions may precipitate acute folate deficiency; folic acid should be given daily. Standard precautions for infusion therapy should be taken. Use as part of total parenteral nutrition in combination with adequate amounts of energy, electrolytes, vitamins and trace elements. Undesirable effects: None known when correctly administered. Infusion via peripheral vein in general can cause thrombophlebitis. Other adverse reactions can occur, see SmPC for details. **Legal Category:** POM. **Marketing Authorisation Holder:** Fresenius Kabi Ltd, Cestrian Court, Eastgate Way, Manor Park, Runcorn, Cheshire WA7 1NT, UK. **Marketing Authorisation Number:** PL 08828/0129 **Package size and cost:** 250ml - £12.00, 500ml - £19.72 1000ml - £55.70 **Further information:** See SmPC for further details. **Adverse events should be reported.** Reporting forms and information can be found at <https://yellowcard.mhra.gov.uk>. Adverse events should also be reported to Fresenius Kabi Limited. **Date of revision:** November 2017.

Vaminolact® solution for infusion (amino acids 65.3g/L)

Active Ingredients: 1000ml contains - Alanine 6.3g, Arginine 4.1g, Aspartic acid 4.1g, Cysteine/cystine 1.0g, Glutamic acid 7.1g, Glycine 2.1g, Histidine 2.1g, Isoleucine 3.1g, Leucine 7.0g, Lysine 5.6g, Methionine 1.3g, Phenylalanine 2.7g, Proline 5.6g, Serine 3.8g, Taurine 0.3g, Threonine 3.6g, Tryptophan 1.4g, Tyrosine 0.5g, Valine 3.6g. **Indications:** Clinical conditions in paediatric patients when enteral supply of protein is insufficient, undesirable or impossible. **Dosage and administration:** For intravenous use only.

Age group (age range)	Dosage range	
	mL/kg bw / day	g AA/kg bw / day
Neonates (birth to <1 month of age)		
Preterm Neonates		
1st Day	23 to 38 mL/kg/d	1.5 to 2.5 g AA/kg/d
≥2nd Day	38 to 54 mL/kg/d	2.5 to 3.5 g AA/kg/d
Term Neonates	23 to 46 mL/kg/d	1.5 to 3.0 g AA/kg/d
Gradual dose increase to the target dose should be used during the first days of infusion		
Infants (≥1 month to <2 years of age)	15 to 38 mL/kg/d	1.0 to 2.5 g AA/kg/d
Children (≥2 years to <12 years of age)	15 to 31 mL/kg/d	1.0 to 2.0 g AA/kg/d
Adolescents (≥12 years to <17 years of age)	15 to 31 mL/kg/d	1.0 to 2.0 g AA/kg/d

BW = Body Weight; AA = Amino acids

The duration of infusion should be at least 8 hours, preferably 12 hours as cyclic infusion or 24 hours as continuous infusion. In neonates and infants, the recommended duration of continuous infusion is 24 hours/d. 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. Adequate energy sources with electrolytes, trace elements and vitamins should be provided. Care to avoid catheterisation complications. Maintain strict asepsis especially in immunocompromised patients. May be infused into a peripheral vein when given simultaneously with a fat emulsion through the same cannula. **Contraindications:** Patients with irreversible liver damage, in severe uraemia where dialysis facilities not available, hypersensitivity to the active substances or excipients. **Special warnings and precautions for use:** Hyperkalaemia, hypernatraemia and acidosis should be corrected prior to commencement of intravenous nutrition. Serum electrolytes, blood glucose levels, and acid base balance and fluid levels should be regularly monitored. Caution in cardiac insufficiency and disturbed protein metabolism; monitor amino acid concentrations in extremely sick, premature and small babies requiring neonatal intensive care whose liver function is likely to be immature and/or disturbed. Folic acid should be given daily as amino acid solutions may precipitate acute folate deficiency. 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. **Undesirable effects:** Nausea may occur rarely. Use of peripheral veins can cause thrombophlebitis. Other adverse reactions can occur (including abnormal liver function

tests, cholestasis), see SmPC for details. **Legal category:** POM **Marketing authorisation number:** PL 8828/0123. **Marketing Authorisation Holder:** Fresenius Kabi Limited, Cestrian Court, Eastgate Way, Manor Park, Runcorn, Cheshire, WA7 1NT, UK. **Package size and cost:** 100ml - £3.70, 500ml - £8.50. **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:** October 2023.

Dipeptiven® concentrate for solution for infusion (N(2)-L-alanyl-L-glutamine)

Active ingredients: 1ml contains: 200mg N(2)-L-alanyl-L-glutamine (= 82.0 mg L-alanine, 134.6 mg L-glutamine). **Indications:** Dipeptiven is indicated as part of a clinical nutrition regimen in patients in hypercatabolic and/or hypermetabolic states. It should be given together with parenteral or enteral nutrition or a combination of both. **Dosage and administration:** For infusion only after mixture with a compatible infusion solution. Adults: Dosage depends on severity of catabolic state and amino acids/protein requirement. Maximum daily dosage of 2g amino acids and/or protein per kg bodyweight should not be exceeded in parenteral/enteral nutrition. Alanine and glutamine supply in Dipeptiven should be taken into consideration. Proportion of amino acids supplied by Dipeptiven should not exceed approx. 30% of the total amino acids/protein supply. Adult dosage: 1.5 - 2.5ml/kg body weight/day. The maximum daily dose of 0.5g N(2)-L-alanyl-L-glutamine (equivalent to 2.5ml Dipeptiven) per kg bodyweight should be administered in combination with at least 1.0g amino acids/protein per kg bodyweight/day. The duration of use should not exceed 3 weeks. When administered as part of total parenteral nutrition, the infusion rate depends on that of the carrier solution and should not exceed 0.1g amino acids/kg body weight/hour. Mix with compatible amino acid carrier solution or amino acid containing infusion regimen prior to administration. For patients receiving combined enteral and parenteral nutrition, infusion rate depends on that of the carrier solution and should be adjusted according to proportions of parenteral and enteral nutrition. In total enteral nutrition, Dipeptiven is continuously infused over 20-24 hours/day. For peripheral venous infusion, dilute Dipeptiven to an osmolarity ≤ 800 mosmol/l. Safety and efficacy in children not established. **Contraindications:** Severe renal insufficiency (creatinine clearance <25 ml/minute), severe hepatic insufficiency, circulatory shock, hypoxia, multiple organ failure, severe metabolic acidosis or known hypersensitivity to the active substances or the excipients. **Special warnings and precautions for use:** Only use as part of clinical nutrition, do not administer if the clinical condition does not allow nutrition. Oral or enteral intake of glutamine should be considered when calculating Dipeptiven dose. Regularly monitor liver function parameters in patients with compensated hepatic insufficiency. Use in pregnant women, nursing mothers and children is not recommended. Control serum electrolytes, serum osmolarity, water balance, acid-base status, creatinine clearance, urea, liver function tests and possible

symptoms of hyperammonaemia. Choice of peripheral or central vein depends on final mixture osmolality. Limited experience with use longer than nine days. **Undesirable effects:** None known when correctly administered. Over adverse reactions can occur (including increase in serious side effects in critically ill patients when used without clinical nutrition) - see SmPC. **Legal Category:** POM. **Marketing Authorisation Number:** PL 08828/0154. **Marketing Authorisation Holder:** Fresenius Kabi Ltd, Cestrian Court, Eastgate Way, Manor Park, Runcorn, Cheshire WA7 1NT, UK. **Package Size and Cost:** 100ml £25.93. **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:** September 2024.

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

Active ingredient: Purified Soybean Oil Ph. Eur 20% w/v **Indications:** For use as part of a balanced intravenous feeding regimen in patients who are unable to receive sufficient amounts of nutrients enterally. Intralipid is especially valuable in providing a high energy intake to compensate for increased energy expenditure following trauma, infections and severe burns. **Dosage and administration:** Slow intravenous infusion. During first 10 minutes drip should be adjusted to 20 drops per minute then after half an hour of 25-40 drops per minute gradually increased to final rate. 500ml Intralipid 20% should be given over at least five hours. On first day of infusion advisable to administer 5ml/kg bodyweight (bw). Dosage may be increased to a maximum of 3g fat/kg bw/24 hours. Can be given as a separate infusion or as part of an admixture (approved for physical stability). Dosage and infusion rate should be governed by the patient's ability to utilise fat and in line with the following ranges. Adults - 500- 1000 ml per 24 hours in conjunction with amino acid and carbohydrate solutions. Essential fatty acid deficiency (EFAD) – 4-8% non-protein calories supplied as Intralipid for prevention or correction; substantially increase dose if EFAD associated with stress. Elderly – Caution in the 'frail' elderly and in all patients with poor renal, cardiac or liver function where smaller volumes should be used. Infants - Dosage is governed by the maturity and birth weight of the infant. Check daily infant's ability to eliminate infused fat through measurement of serum triglycerides. If lipaemia present retest after 4 hours. If possible, infuse continuously over 24 hours and use an appropriate pump to maintain constant infusion rate. Mature infants - 0.5-4.0 g fat/kg bw/24 hours (0.10-0.85 ml/kg/hour). Gradually increase dosage over the first week of administration. Premature and low birth weight infants: - Continuous infusion over 24 hours/day. Initially 0.5-1.0 g/kg/24 hours increasing by the same amount every 24 hours up to 2.0 g/kg/24 hours. Only increase to a maximum of 4g/kg/24 hours by careful monitoring of triglyceride levels, liver function tests and oxygen saturation. When used in neonates and children below 2 years, the solution (in bags and administration sets) should be protected from light exposure until administration is completed. Correct electrolyte,

fluid, acid-base imbalance and shock prior to starting intravenous nutrition. In the seriously ill patient specific preliminary investigations and continuous monitoring are essential. Monitor vitamin and trace element levels especially in long-term intravenous nutrition. **Contraindications:** Hypersensitivity to egg, soya or peanut protein, or to any of the active substances or excipients, severe hyperlipidaemia, severe liver insufficiency, hemophagocytic syndrome, and in patients with acute shock. **Special warnings and precautions for use:** Use with caution in conditions of impaired lipid metabolism (check fat elimination daily), in newborns with neonatal hyperbilirubinaemia, and in infants with known or suspected pulmonary hypertension. Monitor platelet count, liver function tests and serum triglyceride concentration in neonates and particularly in prematures on long term parenteral nutrition. Contains soya-bean oil and egg phospholipids which may rarely cause allergic reactions. Cross allergic reaction has been observed between soybean and peanut. Closely monitor the elimination of fat in conditions of impaired lipid metabolism, and in patients given Intralipid for more than one week. Light exposure of solutions for intravenous parenteral nutrition, especially after admixture with trace elements and/or vitamins, may have adverse effects on clinical outcome in neonates, due to generation of peroxides and other degradation products. Intralipid may interfere with certain laboratory measurements if blood sampled before adequate fat clearance from bloodstream (see SmPC). **Undesirable effects:** In rare instances rise in temperature and less frequently shivering, chills and nausea/vomiting (discontinue Intralipid in such cases). Hypersensitivity reactions, respiratory symptoms, circulatory effects, haemolysis, reticulocytosis, abdominal pain, headache, tiredness and priapism have been reported. Other adverse reactions can occur (including fat overload syndrome), see SmPC for details. **Legal Category:** POM. **Marketing Authorisation Holder:** Fresenius Kabi Limited, Cestrian Court, Eastgate Way, Manor Park, Runcorn, Cheshire, WA7 1NT. **Marketing Authorisation Number:** PL 08828/0110. **Package size and cost:** 10x100 ml £62.10, 10x250 ml £101.60, 12x500 ml £162.24. **Further information:** See SmPC for details. **Adverse events should be reported.** Reporting forms and information can be found at <https://yellowcard.mhra.gov.uk>. Adverse events should also be reported to Fresenius Kabi Limited. **Date of revision:** February 2021.

Vamin® 14 Electrolyte-Free solution for infusion (amino acids)

Active Ingredients: 1000ml solution contains - Alanine 12g, Arginine 8.4g, Aspartic acid 2.5g, L-Cysteine/Cystine 420mg, Glutamic acid 4.2g, Glycine 5.9g, L-Histidine 5.1g, Isoleucine 4.2g, Leucine 5.9g, Lysine 6.8g, L-Methionine 4.2g, Phenylalanine 5.9g, Proline 5.1g, Serine 3.4g, L-Threonine 4.2g, L-Tryptophan 1.4g, L-Tyrosine 170mg, Valine 5.5g. **Indications:** Prophylactic or therapeutic treatment of protein depletion, where sufficient enteral feeding is impossible or impracticable. **Dosage and administration:** Intravenous use only. Adults – depending upon patient requirements

up to 1 litre intravenously per 24 hours. Infuse over at least eight hours per litre. In frail elderly patients or those with poor renal, cardiac or liver function, smaller volumes may be required. Infants – can be administered at the physician's discretion. When used in children below 2 years, the solution (in bags and administration sets) should be protected from light exposure until administration is completed. **Contraindications:** Hypersensitivity to the active substances or excipients, irreversible liver damage, and in severe uraemia when dialysis facilities are not available. **Special warnings and precautions for use:** Hyperkalaemia, hypernatraemia and acidosis should be corrected before parenteral nutrition is started. Regularly monitor serum electrolytes, glucose, acid-base balance and fluid balance. Use with caution in patients with disturbances in protein metabolism or volume intolerance due to cardiac insufficiency. Folic acid should be given daily as amino acid solutions may precipitate acute folate deficiency. 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. When used in children below 2 years, Vamin 14 EF should be protected from ambient light until administration is completed. **Undesirable effects:** Vomiting, flushing and sweating may occur rarely. Use of peripheral veins can cause thrombophlebitis. Other adverse reactions can occur, see SmPC for details. **Legal category:** POM **Marketing authorisation number:** PL 08828/0119. **Marketing Authorisation Holder:** Fresenius Kabi Limited, Cestrian Court, Eastgate Way, Manor Park, Runcorn, Cheshire, WA7 1NT, UK. **Package size and cost:** 500ml - £9.48, 1000ml - £16.02. **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:** August 2020.

Vamin® 18 Electrolyte-Free solution for infusion (amino acids)

Active ingredients: 1000ml contains - Alanine 16g, Arginine 11.3g, Aspartic acid 3.4g, L-Cysteine/Cystine 560mg, Glutamic acid 5.6g, Glycine 7.9g, L-Histidine 6.8g, Isoleucine 5.6g, Leucine 7.9g, L-Lysine 9g, L-Methionine 5.6g, Phenylalanine 7.9g, Proline 6.8g, Serine 4.5g, L-Threonine 5.6g, L-Tryptophan 1.9g, L-Tyrosine 230mg, Valine 7.3g. **Indications:** Prophylactic or therapeutic treatment of protein depletion, where sufficient enteral feeding is impossible or impracticable. **Dosage and administration:** Intravenous use only. Adults – depending upon patient requirements up to 1 litre intravenously per 24 hours. Infuse over at least eight hours per litre. In frail elderly patients or those with poor renal, cardiac or liver function, smaller volumes may be required. Infants – can be administered at the physician's discretion. When used in children below 2 years, the solution (in bags and administration sets) should be protected from light exposure until administration is completed. **Contraindications:** Hypersensitivity to the active substances or excipients, irreversible liver damage, and



in severe uraemia when dialysis facilities are not available. **Special warnings and precautions for use:** Use with caution in patients with disturbances in protein metabolism or volume intolerance due to cardiac insufficiency. Hyperkalaemia, hypernatraemia and acidosis should be corrected before parenteral nutrition is started. Regularly monitor serum electrolytes, blood glucose, acid-base balance and fluid levels. Light exposure of solutions for intravenous parenteral nutrition, especially after admixture with trace elements and/or vitamins, may lead to generation of peroxides and other degradation products. When used in children below 2 years, Vamin 18 Electrolyte-Free should be protected from ambient light until administration is completed. Folic acid should be given daily as amino acid solutions may precipitate acute folate deficiency. **Undesirable effects:** Vomiting, flushing and sweating may occur rarely. Use of peripheral veins can cause thrombophlebitis. Other adverse reactions can occur, see SmPC for details. **Legal category:** POM **Marketing authorisation number:** PL 08828/0120. **Marketing Authorisation Holder:** Fresenius Kabi Limited, Cestrian Court, Eastgate Way, Manor Park, Runcorn, Cheshire, WA7 1NT, UK. **Package size and cost:** 500ml - £11.99, 1000ml - £23.38. **Further information:** See the SmPC for further details. **Adverse events should be reported.** Reporting forms and information can be found at <https://yellowcard.mhra.gov.uk> Adverse events should also be reported to Fresenius Kabi Limited. **Date of preparation:** September 2024.

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.
Email: Pharmacovigilance.GB@fresenius-kabi.com