1 NAME OF THE MEDICINE

Glucose monohydrate, alanine, arginine, aspartic acid, glutamic acid, glycine, histidine, isoleucine, leucine, lysine hydrochloride, methionine, phenylalanine, proline, serine, threonine, tryptophan, tyrosine, valine, calcium chloride dihydrate, magnesium sulfate heptahydrate, potassium chloride, sodium acetate trihydrate, sodium glycerophosphate, soya oil.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

KABIVEN is a three-chamber bag of amino acid solution with electrolytes, glucose solution and lipid emulsion for intravenous infusion. The glucose and amino acid solutions are clear solutions while the fat emulsion is white.

The active ingredients are:

- AMINO ACIDS 2.4%: alanine, arginine, aspartic acid, glutamic acid, glycine, histidine, isoleucine, leucine, lysine hydrochloride, methionine, phenylalanine, proline, serine, threonine, tryptophan, tyrosine and valine.
- ELECTROLYTES 0.7%: calcium chloride dihydrate, magnesium sulfate heptahydrate, potassium chloride, sodium acetate trihydrate and sodium glycerophosphate.
- GLUCOSE 6.8%: glucose monohydrate.
- LIPIDS 3.5%: soya oil.

Each bag contains the following different volumes depending on the three pack sizes.

	2400 mL	1920 mL	1440 mL
Glucose (11%)	1475 mL	1180 mL	885 mL
Amino acids and electrolytes (*Vamin 18 Novum)*	500 mL	400 mL	300 mL
Triglycerides (*Intralipid 20%)*	425 mL	340 mL	255 mL

This corresponds to the following compositions.

Active Ingredients (g)	2400 mL	1920 mL	1440 mL
Soya Oil	85	68	51
Glucose monohydrate *Corresponding to glucose (anhydrous)*	178 *162*	143 *130*	107 *97*
Alanine	8.0	6.4	4.8
Arginine	5.6	4.5	3.4
Aspartic acid	1.7	1.4	1.0
Glutamic acid	2.8	2.2	1.7
Glycine	4.0	3.2	2.4
Histidine	3.4	2.7	2.0
Isoleucine	2.8	2.2	1.7
Leucine	4.0	3.2	2.4
Lysine hydrochloride *Corresponding to lysine*	5.6 *4.5*	4.5 *3.6*	3.4 *2.7*
Methionine	2.8	2.2	1.7

Active Ingredients (g)	2400 mL	1920 mL	1440 mL
Phenylalanine	4.0	3.2	2.4
Proline	3.4	2.7	2.0
Serine	2.2	1.8	1.4
Threonine	2.8	2.2	1.7
Tryptophan	0.95	0.76	0.57
Tyrosine	0.12	0.092	0.069
Valine	3.6	2.9	2.2
Calcium chloride dehydrate *Corresponding to calcium chloride*	0.49 *0.37*	0.39 *0.30*	0.29 *0.22*
Potassium chloride	3.0	2.4	1.8
Magnesium sulfate heptahydrate *Corresponding to magnesium sulfate*	1.6 *0.80*	1.3 *0.64*	0.99 *0.48*
Sodium acetate trihydrate *Corresponding to sodium acetate*	4.1 *2.4*	3.3 *2.0*	2.5 *1.5*
Sodium glycerophosphate	2.5	2.0	1.5
Amino acids	57	45	34
Nitrogen	9.0	7.2	5.4
Triglycerides	85	68	51
Carbohydrates: glucose (dextrose) equivalent to glucose anhydrous	162	130	97
Energy content – approx. total (kJ) – approx. total (kcal) – approx. non protein (kJ) – approx. non protein (kcal)	 7140 1700 6300 1500	 5880 1400 5040 1200	 4200 1000 3780 900
Electrolytes (mmol)			
– sodium	53	43	32
– potassium	40	32	24
– magnesium	6.7	5.3	4.0
– calcium	3.3	2.7	2.0
– phosphate	18	14	11
– sulfate	6.7	5.3	4.0
– chloride	78	62	47
– acetate	65	52	39
Osmolality	Approx. 830 mosm/kg water		
Osmolarity	Approx. 750 mosmol/L		
pH	Approx. 5.6		

Excipients with known effect: egg lecithin.

For the full list of excipients, see Section 6.1 List of excipients.

3 PHARMACEUTICAL FORM

Injection, emulsion.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Parenteral nutrition for patients when oral or enteral nutrition is impossible or insufficient or contraindicated.

4.2 Dose and method of administration

The ability to eliminate fat and metabolise glucose should govern the dosage and infusion rate (see Section 4.4 Special warnings and precautions for use).

Dosage

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.

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 requirements are 0.10–0.15 nitrogen/kg body weight (b.w.)/day in the normal nutritional state or in conditions with mild metabolic stress. In patients with moderate to high metabolic stress with or without malnutrition, the requirements are in the range of 0.15–0.30 g nitrogen/kg b.w./day (1.0–2.0 g amino acid/kg b.w./day). The corresponding commonly accepted requirements are 2.0–6.0 g for glucose and 1.0–2.0 g for fat.

The total energy requirement depends on the patient's clinical condition and is most often between 20–30 kcal/kg b.w./day. In obese patients the dose should be based on the estimated ideal weight.

Kabiven G 11% is produced in three sizes intended for patients with moderately increased, basal or low nutritional requirements. To provide total parenteral nutrition, the addition of trace elements, vitamins and supplemental electrolytes may be required.

The dose range of 0.10–0.15 g nitrogen/kg b.w./day (0.7–1.0 g amino acid/kg b.w./day) and a total energy of 20–30 kcal/kg b.w./day corresponds to approximately 27–40 mL Kabiven G 11%/kg b.w./day.

Infusion rate

The maximum infusion rate for glucose is 0.25 g/kg/h.
Amino acid dosage should not exceed 0.1 g/kg/h.
Fat dosage should not provide more than 0.15 g/kg/h.

The infusion rate should not exceed 3.7 mL/kg b.w./hour (corresponding to 0.25 g glucose, 0.09 g amino acid and 0.13 g fat/kg b.w.). The recommended infusion period for individual bags of Kabiven G 11% is 12–24 hours.

Maximum daily dose

40 mL/kg b.w./day. This is equal to one bag (largest size) to a 64 kg-patient and will provide 0.96 g amino acids/kg b.w./day (0.16 g N/kg b.w./day), 25 kcal/kg b.w./day non-protein energy (2.7 g glucose/kg b.w./day and 1.4 g fat/kg b.w./day).

The maximum daily dose varies with the clinical condition of the patient and may even change from day to day.

Method and duration of administration

Intravenous infusion into a central or peripheral vein (see Section 4.8 Adverse effects and Section 5.1 Pharmacological properties, Clinical trials). Infusion may be continued for as long as required by the patient's clinical condition. Kabiven G 11% should be used within 24 hours of preparation.

In order to minimise the risk of thrombophlebitis, daily rotation of infusion site is recommended.

Instructions for use

Use in one person on one occasion only. Contains no antimicrobial preservative. Discard any unused mixture.

Do not use if package is damaged. Kabiven G 11% should only be mixed and used if the solutions are clear and colourless or slightly yellow and if the emulsion is white and homogenous.

The contents of the three separate chambers have to be mixed before use. Mixing of the solutions by opening the seals between the chambers results in the ready-to-use solution. For that purpose pressure must be exerted on one solution chamber by rolling up the bag from one of the side edges until the middle seal opens. After separation of the seals the bag should be inverted on a number of occasions to ensure a homogenous mixture.

After breaking the seals, chemical and physical in-use stability of the mixed three chamber bag has been demonstrated for 24 hours at 25°C.

Aseptic technique must be used to inject additives and the product must be used within 24 hours.

Compatibility

Additives

Only medicinal or nutritional solutions for which compatibility has been documented may be added to Kabiven G 11%.

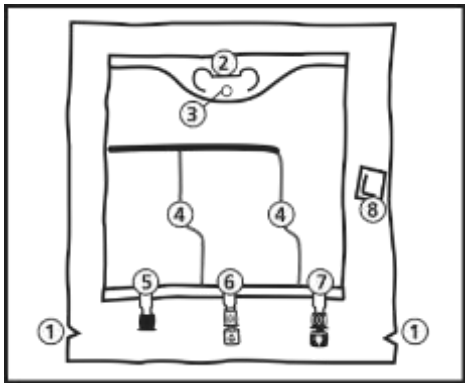
Additions should be made aseptically.

Additions	2400 mL	1920 mL	1440 mL
Soluvit N	1 vial	1 vial	1 vial
Vitalipid N Adult	10 mL	10 mL	10 mL
Up to a total of:			
Sodium	360 mmol	288 mmol	216 mmol
Potassium	360 mmol	288 mmol	216 mmol
Magnesium	12 mmol	9.6 mmol	7.2 mmol
Calcium	12 mmol	9.6 mmol	7.2 mmol
Phosphate	36 mmol	29 mmol	22 mmol

Any mixture remaining after infusion must be discarded.

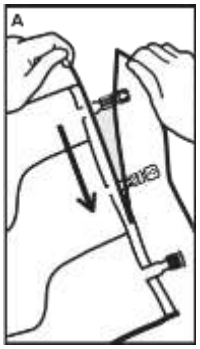
Special Handling Instructions

(1) Notches in the overpouch
(2) Handle
(3) Hole for hanging the bag
(4) Peelable seals
(5) Blind port (only used during Manufacturing)
(6) Additive port
(7) Infusion port
(8) Oxygen absorber



1. Removal of overpouch

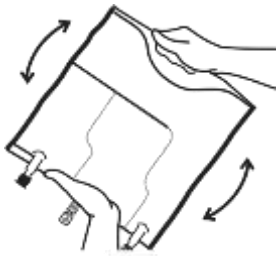
- To remove overpouch, hold the bag horizontally and tear from the notch close to the ports along the upper edge (A).
- Then simply tear the long side, pull off the overpouch and discard it along with the oxygen absorber (B).



2. Mixing

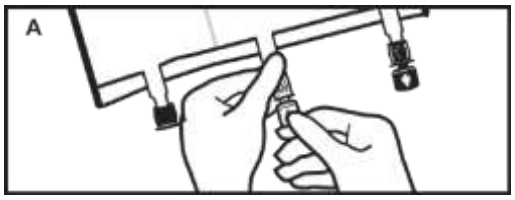
- Place the bag on a flat surface.
- Roll up the bag tightly from the handle side towards the ports, firstly with the right hand and then applying a constant pressure with the left hand until the vertical seals are broken. The vertical peel seals open due to the pressure of the fluid. The peel seals can also be opened before removing the overpouch.
  Please note: The liquids mix easily although the horizontal seal remains closed.

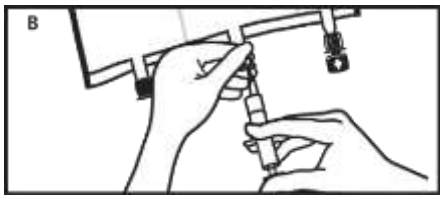
- Mix the contents of the three chambers by inverting the bag three times until the components are thoroughly mixed.



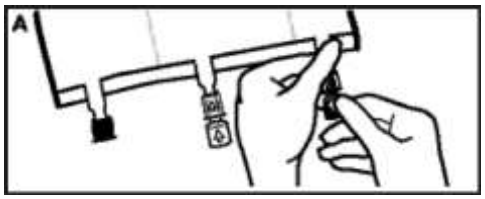
3. Finalising the preparation:

- Place the bag on a flat surface again. Shortly before injecting the additives, break off the tamper-evident arrow flag from the white additive port (A).
  Please note: The membrane in the additive port is sterile.
- Hold the base of the additive port. Insert the needle, inject the additives (with known compatibility) through the centre of the injection site (B).
- Mix thoroughly between each addition by inverting the bag three times. Use syringes with needles of 18–23 gauge and a length of max. 40 mm.



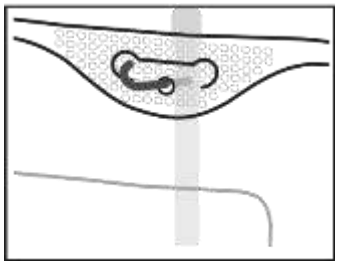


- Shortly before inserting the infusion set, break off the tamper evident arrow flag from the blue infusion port (A).
  Please note: The membrane in the infusion port is sterile.
- Use a non-vented infusion set or close the air-inlet on a vented set.
- Hold the base of the infusion port.
- Push the spike through the infusion port. The spike should be fully inserted to secure it in place.
  Please note: The inner part of the infusion port is sterile.



4. Hanging up the bag

- Hang the bag up by the hole below the handle.



4.3 Contraindications

- Hypersensitivity to egg-, soya- or peanut protein or to any of the ingredients.
- 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 insulin/h
- Pathologically elevated serum levels of any of the included electrolytes
- General contraindications to infusion therapy: acute pulmonary oedema, hyperhydration, decompensated cardiac insufficiency and hypotonic dehydration
- Haemophagocytotic syndrome
- Unstable conditions (e.g. severe post-traumatic conditions, uncompensated diabetes, acute myocardial infarction, metabolic acidosis, severe sepsis and hyperosmolar coma)
- Due to composition, Kabiven G 11% is not suitable for use in new-borns or infants under 2 years of age.

4.4 Special warnings and precautions for use

The 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. The serum concentration of triglycerides should not exceed 3 mmol/L during infusion.

Disturbances of the electrolyte and fluid balance (e.g. abnormally high or low serum levels of the electrolytes) should be corrected before starting the infusion.

Special clinical monitoring is required at the beginning of any intravenous infusion. Should any abnormal sign occur, the infusion must be stopped. Since an increased risk of infection is associated with the use of any central vein, strict aseptic precautions should be taken to avoid any contamination during catheter insertion and manipulation.

Kabiven G 11% should be given with caution in conditions of impaired lipid metabolism, such as in renal insufficiency, uncompensated diabetes mellitus, pancreatitis, impaired liver function, hypothyrodism (with hypertriglyceridaemia) and sepsis. If Kabiven G 11% is given to patients with these conditions, close monitoring of serum triglycerides is mandatory.

Serum glucose, electrolytes and osmolarity as well as fluid balance, acid-base status and liver enzyme tests (alkaline phosphatase, ALT, AST) should be monitored.

Blood cell count and coagulation should be monitored when fat is given for a longer period.

In patients with renal insufficiency, the phosphate and potassium intake should be carefully controlled to prevent hyperphosphataemia and hyperkalaemia.

The amount of individual electrolytes to be added is governed by the clinical condition of the patient and by frequent monitoring of serum levels.

Parenteral nutrition should be given with caution in metabolic acidosis, lactic acidosis, insufficient cellular oxygen supply and increased serum osmolarity.

Kabiven G 11% should be given with caution to patients with a tendency towards electrolyte retention.

Any sign or symptom of anaphylactic reaction (such as fever, shivering, rash or dyspnoea) should lead to immediate interruption of the infusion.

Intravenous infusion of amino acids is accompanied by increased urinary excretion of the trace elements copper and, in particular, zinc. This should be considered in the dosing of trace elements, especially during long-term intravenous nutrition.

In malnourished patients, initiation of parenteral nutrition can precipitate fluid shifts resulting in pulmonary oedema and congestive heart failure as well as a decrease in the serum concentration of potassium, phosphorus, magnesium and water-soluble vitamins. These changes can occur within 24 to 48 hours. Careful and slow initiation of parenteral nutrition is recommended together with close monitoring and appropriate adjustments of fluid, electrolytes, minerals and vitamins.

Kabiven G 11% should not be given simultaneously with blood in the same infusion set due to the risk of pseudoagglutination.

In patients with hyperglycaemia, administration of exogenous insulin might be necessary.

Kabiven G 11% contains soya oil and egg lecithin which may rarely cause allergic reactions. Cross allergic reaction has been observed between soya-bean and peanut.

Peripheral infusion

As with all hypertonic solutions, thrombophlebitis may occur if peripheral veins are used for infusions. Several factors contribute to the incidence of thrombophlebitis. These include the type of cannula used and its diameter and length, the duration of infusion, pH and osmolality of infusates, infection and the number of manipulations. It is recommended that venous access sites for TPN should not be used for other intravenous additives or solutions (see Section 5.1 Pharmacological properties, Clinical trials).

Use in the elderly

No data available.

Paediatric use

Kabiven G 11% is not recommended to neonates and infants under 2 years of age.

Effects on laboratory tests

The fat content of Kabiven G 11% may interfere with certain laboratory measurements (e.g. bilirubin, lactate dehydrogenase, oxygen saturation, and haemoglobin) if blood is sampled before fat has been adequately cleared from the bloodstream. Fat is cleared after a fat-free interval of 5–6 hours in most patients.

4.5 Interaction with other medicines and other forms of interaction

Heparin given in clinical doses causes a transient release of lipoprotein lipase into the circulation. This may result initially in increased plasma lipolysis followed by a transient decrease in triglyceride clearance.

Other drugs, like insulin, may influence lipase activity but there is no evidence to suggest that this adversely affects therapeutic value.

Soya oil has a natural content of vitamin K_1. This may interfere with the therapeutic effect of coumarin derivatives, which should be closely monitored in patients treated with such drugs.

There are no clinical data to show that any of the above listed interactions are of definite clinical relevance.

4.6 Fertility, pregnancy and lactation

Effects on fertility

No data available.

Use in pregnancy

Category: Exempt

Reproduction studies in animals have not been conducted with Kabiven G 11%. No clinical data are currently available to assess the safety of Kabiven G 11% in pregnancy. The prescriber should consider the benefit/risk relationship before administering Kabiven G 11% to pregnant women.

Use in lactation

No clinical data are currently available on the use of Kabiven G 11% in breast-feeding women. Following intravenous infusion, most of the active ingredients contained in Kabiven G 11% are expected to be excreted into human milk, and the safety to the breast-feeding infant has not been adequately established. The prescriber should consider the benefit/risk relationship before administering Kabiven G 11% to breast-feeding women.

4.7 Effects on ability to drive and use machines

The effects of this medicine on a person's ability to drive and use machines were not assessed as part of its registration.

4.8 Adverse effects (Undesirable effects)

The infusion may cause a rise in body temperature (incidence < 3%) and, less frequently, shivering, chills and nausea/vomiting (incidence < 1%). Transient increases in liver enzymes during intravenous nutrition have also been reported.

Thrombophlebitis is probably the most common adverse event in patients in general surgical wards. The cause is in most cases due to infusions of saline, glucose or similar fluids and drugs. The development of thrombophlebitis is dependent on many factors, which are listed below:

- Osmolarity of the injected substance
- pH of the injected substance
- Chemical structure of the injected substance
- Amount of blood flow
- Size of the blood vessel
- Presence of protective drugs or substances
- Duration of injection/infusion
- Speed of injection/infusion
- Material of the catheter
- Size of the catheter
- Movement of the catheter
- Microbiological agents

The rate of thrombophlebitis with Kabiven G 11% from post-marketing surveillance is estimated to be common (> 1/100). The risks of thrombophlebitis should be weighed against the benefits when peripheral administration is intended.

Reports of other undesirable effects in conjunction with the included components are extremely rare. Hypersensitivity reactions (anaphylactic reaction, skin rash, urticaria), respiratory symptoms (e.g. tachypnoea) and hyper/hypotension have been described. Haemolysis, reticulocytosis, abdominal pain, headache, tiredness and priapism have been reported.

Fat overload syndrome

An impaired capacity to eliminate fat may lead to the fat overload syndrome. This may occur as a result of overdosage, but also at recommended rates of infusion, in association with a sudden change in the patient's clinical condition resulting in severe renal or hepatic impairment.

The fat overload syndrome is characterised by hyperlipaemia, fever, fat infiltration, hepatomegaly, splenomegaly, anaemia, leucopenia, thrombocytopenia, blood coagulation disorders and coma. These changes are invariably reversible on discontinuation of the fat infusion.

Reporting suspected adverse effects

Reporting suspected adverse reactions after registration of the medicinal product is important. It allows continued monitoring of the benefit-risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions at www.tga.gov.au/reporting-problems.

4.9 Overdose

See Fat overload syndrome under Section 4.8 Adverse effects.

Nausea, vomiting and sweating have been observed during infusion of amino acids at rates exceeding the recommended maximum rate.

If symptoms of overdose occur, the infusion should be slowed down or discontinued.

Additionally, overdose might cause fluid overload, electrolyte imbalances, hyperglycaemia, and hyperosmolality.

In some rare serious cases, haemodialysis, haemofiltration or haemo-diafiltration may be necessary.

For information on the management of overdose, contact the Poisons Information Centre on 13 11 26 (Australia).

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Mechanism of action

Fat emulsion

Intralipid, the fat emulsion used in Kabiven G 11% provides essential and non-essential long chain fatty acids for energy metabolism and the structural integrity of cell membranes.

Intralipid in the recommended dosage does not cause haemodynamic changes. No clinically significant changes in pulmonary function have been described when Intralipid is used properly. The transient increase in liver enzymes seen in some patients on parenteral nutrition is reversible and disappears when parenteral nutrition is discontinued. Similar changes are also seen in parenteral nutrition without fat emulsions.

Amino acids and electrolytes

The amino acids, constituents of protein in ordinary food, are utilised for tissue protein synthesis and any surplus is channelled to a number of metabolic pathways. Studies have shown a thermogenic effect of amino acid infusion.

Glucose

Glucose should have no pharmacodynamic effects apart from contributing to maintain or replete the normal nutritional status.

Clinical trials

There was an open, randomised, comparative clinical study comparing the safety/tolerance of Kabiven G 11% with a compounded intravenous TPN preparation. A total of 46 subjects requiring total parenteral nutrition and appropriate for infusion in a peripheral vein were evaluated. One bag of Kabiven G 11% 2400 mL or trial medication was administered over 12–24 hours daily at an infusion rate not exceeding 4.2 mL/kg bw/hour. Moderate or worse venous reactions (pain, swelling, redness, palpable vein cord) were seen in fifteen patients who received Kabiven G 11% versus nine who received the compounded preparation. The evaluation of clinical and laboratory safety parameters, adverse events and local tolerance demonstrated that the two trial products were equally safe and well tolerated.

5.2 Pharmacokinetic properties

Fat emulsion

Intralipid has biological properties similar to those of endogenous chylomicrons. Unlike chylomicrons, Intralipid does not contain cholesterol esters or apolipoproteins, while its phospholipid content is significantly higher.

Intralipid is eliminated from the circulation via a pathway similar to that of endogenous chylomicrons, at least early on in the catabolism. The exogenous fat particle is primarily hydrolysed in the circulation and taken up by the LDL receptors peripherally and by the liver. The elimination rate is determined by the composition of the fat particles, the nutritional status, the disease and the rate of infusion. In healthy volunteers, the maximum clearance rate of Intralipid after fasting overnight is equivalent to 3.8 ± 1.5 g of triglyceride per kg body weight per 24 hours.

Both the elimination and the oxidation rates are dependent on the patient's clinical condition; elimination is faster and utilisation is increased in postoperative patients and in trauma, while patients with renal failure and hypertriglyceridaemia show lower utilisation of exogenous fat emulsions.

Amino acids and electrolytes

The pharmacokinetic properties of the infused amino acids and electrolytes are essentially the same as for amino acids and electrolytes supplied by ordinary food. However, the amino acids of dietary protein first enter the portal vein and then the systemic circulation, while intravenously infused amino acids reach the systemic circulation directly. This difference results only in a marginal change of kinetics and does not change the bioavailability of the amino acids.

Glucose

The pharmacokinetic properties of infused glucose are essentially the same as those of glucose supplied by ordinary food.

5.3 Preclinical safety data

Genotoxicity

No study has been conducted to examine the mutagenic potential of Kabiven G 11%. The effects of Kabiven G 11% have not been investigated in animal studies.

Carcinogenicity

No study has been conducted to examine the carcinogenic potential of Kabiven G 11%. The effects of Kabiven G 11% have not been investigated in animal studies.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- Egg lecithin
- Glycerol
- Sodium hydroxide
- Glacial acetic acid
- Water for injections

6.2 Incompatibilities

Kabiven G 11% may only be mixed with other medicinal products for which compatibility has been documented (refer Section 4.2, Dose and method of administration, Compatibilities, Additives).

6.3 Shelf life

In Australia, information on the shelf life can be found on the public summary of the Australian Register of Therapeutic Goods (ARTG). The expiry date can be found on the packaging.

6.4 Special precautions for storage

Store below 25°C. Store in overpouch. Do not freeze.

6.5 Nature and contents of container

The container consists of a multi-chamber inner bag and an overpouch. The inner bag is separated into three chambers by peelable seals. An oxygen absorber is placed between the inner bag and the overpouch.

The inner bag is made of a multilayer polymer film, Biofine, consisting of poly(propylene-co-ethylene), synthetic rubber poly[styrene-block-(butylene-co-ethylene)] (SEBS) and synthetic rubber poly(styrene-block-isoprene) (SIS).

The infusion and additive ports are made of polypropylene and synthetic rubber poly[styrene-block-(butylene-co-ethylene)] (SEBS) equipped with synthetic polyisoprene (latex-free) stoppers.

The blind port, which is only used during manufacturing, is made of polypropylene equipped with a synthetic polyisoprene (latex-free) stopper.

Pack sizes:
1 × 1440 mL, 4 × 1440 mL (AUST R 97893)
1 × 1920 mL, 4 × 1920 mL (AUST R 97894)
1 × 2400 mL, 3 × 2400 mL (AUST R 97895)

6.6 Special precautions for disposal

In Australia, any unused medicine or waste material should be disposed of in accordance with local requirements.

6.7 Physicochemical properties

CAS numbers

- *Amino acids:* alanine (56-41-7), arginine (74-79-3), aspartic acid (6899-03-2), glutamic acid (56-86-0), glycine (56-40-6), histidine (71-00-1), isoleucine (73-32-5), leucine (61-90-5), lysine hydrochloride (657-27-2), methionine (63-68-3), phenylalanine (63-91-2), proline (147-85-3), serine (56-45-1), threonine (72-19-5), tryptophan (73-22-3), tyrosine (60-18-4), valine (72-18-4).
- *Electrolytes*: calcium chloride dihydrate (10035-04-8), magnesium sulfate heptahydrate (10034-99-8), potassium chloride (7447-40-7), sodium acetate trihydrate (6131-90-4), sodium glycerophosphate (1334-74-3).
- *Glucose*: glucose monohydrate (5996-10-1).
- *Lipids:* soya oil (8001-22-7).

7 MEDICINE SCHEDULE (POISONS STANDARD)

Not scheduled.

8 SPONSOR

Fresenius Kabi Australia Pty Limited
Level 2, 2 Woodland Way
Mount Kuring-gai NSW 2080

Telephone: (02) 9391 5555

9 DATE OF FIRST APPROVAL

20 July 2004

10 DATE OF REVISION

15 November 2019

Summary Table of Changes

Section changed	Summary of new information
n.a.	reformatted PI