SMOFKABIVEN PERIPHERAL
Emulsion for Infusion

Composition
SmofKabiven Peripheral consists of a three chamber bag system. Each bag contains the following partial volumes depending on the two pack sizes.

	1448ml	1904ml	Per 1000 ml
Glucose 13%	788 ml	1036ml	544 ml
Amino acid solution with electrolytes	456 ml	600 ml	315 ml
Lipid emulsion	204 ml	268 ml	141 ml

This corresponds to the following total compositions:

Active ingredients	1448 ml	1904 ml	Per 1000 ml
Glucose (as monohydrate)	103 g	135 g	71 g
Alanine	6.4 g	8.4 g	4.4 g
Arginine	5.5 g	7.2 g	3.8 g
Glycine	5.1 g	6.6 g	3.5 g
Histidine	1.3 g	1.8 g	0.93 g
Isoleucine	2.3 g	3.0 g	1.6 g
Leucine	3.3 g	4.4 g	2.3 g
Lysine (as acetate)	3.0 g	4.0 g	2.1 g
Methionine	1.9 g	2.6 g	1.3 g
Phenylalanine	2.3 g	3.1 g	1.6 g
Proline	5.1 g	6.7 g	3.5 g
Serine	3.0 g	3.9 g	2.1 g
Taurine	0.46 g	0.60 g	0.32 g
Threonine	2.0 g	2.6 g	1.4 g
Tryptophan	0.91 g	1.2 g	0.63 g
Tyrosine	0.17 g	0.24 g	0.12 g
Valine	2.9 g	3.7 g	2.0 g
Calcium chloride (as dihydrate)	0.26 g	0.34 g	0.18 g
Sodium glycerophosphate (as hydrate)	1.9 g	2.5 g	1.3 g
Magnesium sulphate (as heptahydrate)	0.55 g	0.72 g	0.38 g
Potassium chloride	2.0 g	2.7 g	1.4 g
Sodium acetate (as trihydrate)	1.6 g	2.0 g	1.1 g
Zinc sulphate (as heptahydrate)	0.006 g	0.008 g	0.004 g
Soya-bean oil, refined	12.3 g	16.1 g	8.5 g
Medium-chain triglycerides	12.3 g	16.1 g	8.5 g
Olive oil, refined	10.1 g	13.4 g	7.0 g
Fish oil, rich in omega-3-acids	6.1 g	8.0 g	4.2 g

Corresponding to

	1448 ml	1904 ml	Per 1000 ml
• Carbohydrates			
- Glucose (anhydrous)	103 g	135 g	71 g
• Amino acids	46 g	60 g	32 g
• Nitrogen	7.4 g	9.8 g	5.1 g
• Lipids	41 g	54 g	28 g
• Energy content			
- total (approx.)	1000 kcal 4.0 MJ	1300 kcal 5.4 MJ	700 kcal 2.9 MJ
- non protein (approx.)	800 kcal 3.5 MJ	1100 kcal 4.6 MJ	600 kcal 2.5 MJ
• Electrolytes			
- sodium	36 mmol	48 mmol	25 mmol
- potassium	28 mmol	36 mmol	19 mmol
- magnesium	4.6 mmol	6.0 mmol	3.2 mmol
- calcium	2.3 mmol	3.0 mmol	1.6 mmol
- phosphate[1]	11.9 mmol	15.6 mmol	8.2 mmol
- zinc	0.03 mmol	0.05 mmol	0.02 mmol
- sulphate	4.6 mmol	6.1 mmol	3.2 mmol
- chloride	32 mmol	42 mmol	22 mmol
- acetate	96 mmol	125 mmol	66 mmol
• Osmolality	approx. 950 mosmol/kg water		
• Osmolarity	approx. 850 mosmol/l		
• PH (after mixing)	approx. 5.6		

[1] Contribution from both the lipid emulsion and the amino acid solution.

Excipients
Glycerol, Purified egg phospholipids, all-*rac*-α-Tocopherol, Sodium hydroxide (pH adjuster), Sodium oleate, Acetic acid, glacial (pH adjuster), Water for injections.

Pharmaceutical Form
Emulsion for infusion

Glucose and amino acid solutions are clear and colourless to slightly yellow and free from particles. The lipid emulsion is white and homogenous.

Therapeutic indications
Parenteral nutrition for adult patients when oral or enteral nutrition is impossible, insufficient or contraindicated.

Posology and method of administration
The appearance of the product after mixing the 3 chambers is a white emulsion.

The patient's ability to eliminate fat and metabolise nitrogen and glucose, and the nutritional

requirements should govern the dosage and infusion rate, see section 'Special warnings and precautions for use'

The dose should be individualised with regard to the patient's clinical condition and body weight (bw).
The nitrogen requirements for maintenance of body protein mass depend on the patient's condition (e.g. nutritional state and degree of catabolic stress or anabolism).

The requirements are 0.10-0.15 g nitrogen/kg bw/day (0.6-0.9 g amino acids/kg bw/day) in the normal nutritional state or in conditions with mild catabolic stress. In patients with moderate to high metabolic stress with or without malnutrition, the requirements are in the range of 0.15-0.25 g nitrogen/kg bw/day (0.9-1.6 g amino acids/kg bw/day). In some very special conditions (e.g. burns or marked anabolism) the nitrogen need may be even higher.

Dosage
The dosage range of 20 ml – 40 ml SmofKabiven Peripheral/kg bw/day corresponds to 0.10-0.20 g nitrogen/kg bw/day (0.6-1.3 g amino acids/kg bw/day) and 14-28 kcal/kg bw/day of total energy (11-22 kcal/kg bw/day of non-protein energy). This covers the need of the majority of the patients. In obese patients the dose should be based on the estimated ideal weight.

Infusion rate
The maximum infusion rate for glucose is 0.25 g/kg bw/h, for amino acid 0.1 g/kg bw/h, and for fat 0.15 g/kg bw/h.

The infusion rate should not exceed 3.0 ml/kg bw/h (corresponding to 0.21 g glucose, 0.10 g amino acids, and 0.08 g fat/kg bw/h). The recommended infusion period is 14-24 hours.

Maximum daily dose
The maximum daily dose varies with the clinical condition of the patient and may even change from day to day. The recommended maximum daily dose is 40 ml/kg bw/day.

The recommended maximum daily dose of 40 ml/kg bw/day will provide 0.20 g nitrogen/kg bw/day (corresponding to 1.3 g amino acids/kg bw/day), 2.8 g glucose/kg bw/day, 1.1 g fat/kg bw/day and a total energy of 28 kcal/kg bw/day (corresponding to 22 kcal/kg bw/day of non-protein energy).

Method and duration of administration
Intravenous use, infusion into a peripheral or central vein.

SmofKabiven Peripheral is available in three pack sizes intended for patients with moderately increased or basal nutritional requirements. To provide total parenteral nutrition, trace elements, vitamins and possibly electrolytes (taking into account the electrolytes already present in SmofKabiven Peripheral) should be added to SmofKabiven Peripheral according to the patients need.

Pediatric patients
SmofKabiven Peripheral is not recommended for use in children and adolescent (age below 18 years old), see section 'Special warnings and precautions for use'.

Contraindications

- Hypersensitivity to fish-, egg-, soya- or peanut protein or to any of the active substances or excipients
- Severe hyperlipidemia
- 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, and decompensated cardiac insufficiency
- Hemophagocytotic syndrome
- Unstable conditions (e.g. severe post-traumatic conditions, uncompensated diabetes mellitus, acute myocardial infarction, stroke, embolism, metabolic acidosis, severe sepsis, hypotonic dehydration and hyperosmolar coma)

Special warnings and precautions for use

The capacity to eliminate fat is individual and should therefore be monitored according to the routines of the clinician. This is in general done by checking the triglyceride levels. The concentration of triglycerides in serum should not exceed 4 mmol/l during infusion. An overdose may lead to fat overload syndrome, see section 'Undesirable effects'.

SmofKabiven Peripheral should be given with caution in conditions of impaired lipid metabolism, which may occur in patients with renal failure, diabetes mellitus, pancreatitis, impaired liver function, hypothyroidism and sepsis.

This medicinal product contains soya-bean oil, fish oil and egg phospholipids, which may rarely cause allergic reactions. Cross allergic reactions has been observed between soya-bean and peanut.

To avoid risks associated with too rapid infusion rates, it is recommended to use a continuous and well-controlled infusion, if possible by using a volumetric pump.

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.

SmofKabiven Peripheral should be given with caution to patients with a tendency towards electrolyte retention. 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 peripheral vein, strict aseptic precautions should be taken to avoid any contamination during catheter insertion and manipulation.

Serum glucose, electrolytes and osmolarity as well as fluid balance, acid-base status and liver enzyme tests 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 hyperphosphatemia 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 lactic acidosis, insufficient cellular oxygen supply and increased serum osmolarity.

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

The fat content of SmofKabiven Peripheral may interfere with certain laboratory measurements (e.g. bilirubin, lactate dehydrogenase, oxygen saturation, hemoglobin) 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.

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

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, therefore careful and slow initiation of parenteral nutrition is recommended in this patient group, together with close monitoring and appropriate adjustments of fluid, electrolytes, minerals and vitamins.

Smofkabiven should not be given in the same infusion site as for blood transfer due to the risk of pseudoaglutination.

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

Thrombophlebitis may occur if peripheral veins are used for infusions. The catheter insertion site should be evaluated daily for local signs of thrombophlebitis.

Due to composition of the amino acid solution in SmofKabiven Peripheral it is not suitable for the use in new-borns or infants below 2 years of age. There is at present no clinical experience of the use of SmofKabiven Peripheral in children and adolescents (age below 18 years old).

Interactions with other medicinal products and other forms of interaction
Some medicinal products, like insulin, may interfere with the body's lipase system. This kind of interaction seems, however, to be of limited clinical importance.

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.

Soya-bean oil has a natural content of vitamin K_1. However, the concentration in SmofKabiven Peripheral is so low that it is not expected to significantly influence the coagulation process in patients treated with coumarin derivatives.

Pregnancy and lactation

There are no data available on exposure of SmofKabiven Peripheral in pregnant or breast-feeding women. There are no studies available on reproductive toxicity in animals. Parenteral nutrition may become necessary during pregnancy and lactation. SmofKabiven Peripheral should only be given to pregnant and breast-feeding women after careful consideration.

Effects on ability to drive and use machines
Not relevant

Undesirable effects

	Common >1/100, <1/10	*Uncommon >1/1000, <1/100*	*Rare >1/10000, <1/1000*
Cardiac disorders			Tachycardia
Respiratory, thoracic and mediastinal disorders			Dyspnoea
Gastrointestinal disorders		Lack of appetite, nausea, vomiting	
Metabolism and nutrition disorders		Elevated plasma levels of liver enzymes	
Vascular disorders	Thrombophlebitis		Hypotension, hypertension
General disorders and administration site conditions	Slight increase in body temperature, inflammation at injection site	Chills, dizziness, headache	Hypersensitivity-reactions (e.g. anaphylactic or anaphylactoid reactions, skin rash, urticaria, flush, headache), heat or cold sensation, paleness, cyanosis, pain in the neck, back, bones, chest and loins

Should these side-effects occur the infusion of SmofKabiven Peripheral should be stopped or, if necessary, continued at a reduced dosage.

Fat overload syndrome
Impaired capacity to eliminate triglycerides can lead to "Fat overload syndrome" which may be caused by overdose. Possible signs of metabolic overload must be observed. The cause may be genetic (individually different metabolism) or the fat metabolism may be affected by ongoing or previous illnesses. This syndrome may also appear during severe hypertriglyceridemia, even at the recommended infusion rate, and in association with a sudden change in the patient's clinical condition, such as renal function impairment or infection. The fat overload syndrome is characterised by hyperlipemia, fever, fat infiltration, hepatomegaly with or without icterus, splenomegaly, anemia, leukopenia, thrombocytopenia, coagulation disorder, hemolysis and reticulocytosis, abnormal

liver function tests and coma. The symptoms are usually reversible if the infusion of the lipid emulsion is discontinued.

Excess of amino acid infusion
As with other amino acid solutions, the amino acid content in SmofKabiven Peripheral may cause undesirable effects when the recommended infusion rate is exceeded. These effects are nausea, vomiting, shivering and sweating. Amino acid infusion may also cause a rise in body temperature. With an impaired renal function, increased levels of nitrogen containing metabolites (e.g. creatinine, urea) may occur.

Excess of glucose infusion
If the glucose clearance capacity of the patient is exceeded, hyperglycaemia will develop

Overdose

See section 'Undesirable effects' "Fat overload syndrome", "Excess of amino acid infusion" and "Excess of glucose infusion".

If symptoms of overdose of fat or amino acids occur, the infusion should be slowed down or discontinued. There is no specific antidote for overdose. Emergency procedures should be general supportive measures, with particular attention to respiratory and cardiovascular systems. Close biochemical monitoring would be essential and specific abnormalities treated appropriately.

If hyperglycaemia occurs, it should be treated according to the clinical situation either by appropriate insulin administration and/or adjustment of the infusion rate.

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

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

Pharmacodynamic properties
Pharmacotherapeutic group: Solutions for parenteral nutrition.
ATC code: B05BA10

Lipid emulsion
The lipid emulsion of SmofKabiven Peripheral is composed of Smoflipid and has a particle size and biological properties similar to those of endogenous chylomicrons. The constituents of Smoflipid; soya-bean oil, medium-chain triglycerides, olive oil and fish oil have except for their energy contents, their own pharmacodynamic properties.

Soya-bean oil has a high content of essential fatty acids. The omega-6 fatty acid linoleic acid is the most abundant (approx. 55-60%). Alpha-linolenic acid, an omega-3 fatty acid, constitutes about 8 %. This part of SmofKabiven Peripheral provides the necessary amount of essential fatty acids.

Medium-chain fatty acids are rapidly oxidised and provide the body with a form of immediately available energy.

Olive oil mainly provides energy in the form of mono-unsaturated fatty acids, which are much less prone to peroxidation than the corresponding amount of poly-unsaturated fatty acids.

Fish oil is characterised by a high content of eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA). DHA is an important structural component of cell membranes, whereas EPA is a precursor of eicosanoids as prostaglandines, thromboxanes and leukotrienes.

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.

Pharmacokinetic properties

Lipid emulsion

The individual triglycerides in Smoflipid have different clearance rate but Smoflipid as a mixture is eliminated faster than long chain triglycerides (LCT). Olive oil has the slowest clearance rate of the components (somewhat slower than LCT) and medium chain triglycerides (MCT) the fastest. Fish oil in a mixture with LCT has the same clearance rate as LCT alone.

Amino acids and electrolytes

The principal 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.

Glucose

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

Preclinical safety data

Preclinical safety studies with SmofKabiven Peripheral have not been performed. However, preclinical data for Smoflipid as well as for amino acid and glucose solutions of various concentrations and sodium glycerophosphate reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity and genotoxicity. No teratogenic effects or other embryotoxic injuries could be observed in rabbits with amino acid solutions and are not to be expected from fat emulsions and sodium glycerophosphate when giving at the recommended doses as substitution therapy. Nutritional products (amino acid solutions, fat emulsions, and sodium glycerophosphate) used in replacement therapy at physiological levels are not expected to be embryotoxic, teratogenic, or to influence reproductive performance or fertility.

In a test on guinea pigs (maximisation test) fish oil emulsion showed moderate dermal sensitisation. A systemic antigenicity test gave no indication of evidence of anaphylactic potential of fish oil.

In a local tolerance study in rabbits with SmofLipid a slight, transient inflammation after intra-arterial, paravenous or subcutaneous administration was observed. After intra-muscular administration a moderate transient inflammation and tissue necrosis were seen in some animals.

Incompatibilities

SmofKabiven Peripheral may only be mixed with other medicinal products for which compatibility has been documented.

Shelf-life

Shelf-life of the medicinal product as packaged for sale

2 years

Shelf-life after mixing

Chemical and physical in-use stability of the mixed three chamber bag has been demonstrated for 36 hours at 25°C. From a microbiological point of view the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2-8°C.

Shelf-life after mixing with additives

From a microbiological point of view, the product should be used immediately when additions have been made. If not used immediately, the in-use storage time and conditions prior to use are the responsibility of the user and should normally not be longer than 24 hours at 2-8°C.

Special precautions for storage

Do not store above 25°C. Do not freeze. Store in overpouch.

Shelf life after mixing: See section 'Shelf-life'
Shelf life after mixing with additives: See section 'Shelf-life'

Nature and contents of container

The container consists of a multichamber 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, alternative Excel or Biofine.

The Biofine inner bag film consists of Poly(propylene-co-ethylene), synthetic rubber poly[styrene-block-(butylene-co-ethylene0] (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-ethylene0] (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:

Biofine
1 x 1448 ml
1 x 1904 ml

Special precaution for disposal

Instructions for use
Do not use if package is damaged. Use only if the amino acid and glucose solutions are clear and colourless or slightly yellow and the lipid emulsion is white and homogenous. The contents of the three separate chambers have to be mixed before use, and before any additions are made via the additive port.

After separation of the peelable seals the bag should be inverted on a number of occasions to ensure a homogenous mixture, which does not show any evidence of phase separation.

Compatibility
Only medicinal or nutrition solutions for which compatibility has been documented may be added to SmofKabiven Peripheral. Compatibility for different additives and the storage time of the different admixtures will be available upon request.

Addition should be made aseptically.

For single use only. Any mixture remaining after infusion must be discarded.

PRESCIPTION ONLY

Manufacture by :
Fresenius Kabi Sweden AB, Uppsala, Sweden

Imported by:
Fresenius Kabi Combiphar
Bandung-Indonesia

Reg. No:

INFORMASI PRODUK UNTUK PASIEN

SMOFKABIVEN PERIPHERAL

Emulsi Untuk Infus

Baca keseluruhan isi leaflet dengan hati-hati sebelum anda menggunakan obat ini.

- Simpan leaflet ini. anda mungkin perlu untuk membacanya lagi.
- Jika anda memiliki pertanyaan lebih lanjut, silahkan bertanya kepada dokter atau apoteker anda.
- Jika ada efek samping yang serius, atau jika anda merasakan adanya efek samping yang tidak tercantum dalam leaflet ini, tolong sampaikan pada dokter atau apoteker anda.

Dalam leaflet ini tercantum :

1. Apa SmofKabiven Peripheral dan apa kegunaannya
2. Sebelum anda menggunakan SmofKabiven Peripheral
3. Bagaimana menggunakan SmofKabiven Peripheral
4. Efek samping yang mungkin terjadi
5. Bagaimana penyimpanan SmofKabiven Peripheral
6. Informasi lebih lanjut

1. APA SMOFKABIVEN PERIPHERAL DAN APA KEGUNAANNYA

SmofKabiven Peripheral adalah suatu emulsi untuk infus yang diberikan ke dalam darah melalui drip (infus intravena). SmofKabiven Peripheral mengandung glukosa (karbohidrat), asam amino (komponen yang digunakan untuk membangun protein), garam-garam (elektrolit), dan lipid (lemak) dalam sebuah wadah plastik.

Tenaga ahli kesehatan akan memberikan anda SmofKabiven Peripheral ketika pemberian makanan dengan cara lain tidak cukup atau tidak berhasil.

2. SEBELUM ANDA MENGGUNAKAN SMOFKABIVEN PERIPHERAL

Jangan menggunakan SmofKabiven Peripheral :

- jika anda alergi (hipersensitif) terhadap komponen dalam SmofKabiven Peripheral
- jika anda alergi terhadap ikan atau telur
- jika anda alergi terhadap kacang-kacangan atau kedelai, anda tidak boleh menggunakan produk ini. SmofKabiven Peripheral mengandung minyak kacang kedelai
- jika anda memiliki kadar lemak berlebih dalam darah (hiperlipidemia)
- jika anda memiliki penyakit hati yang berat
- jika anda memiliki gangguan pembekuan darah (penyakit koagulasi)
- jika anda memiliki masalah dalam mengunakan asam amino
- jika anda memiliki penyakit ginjal yang parah tanpa akses dialisis
- jika anda dalam kondisi syok akut
- jika anda memiliki kadar gula berlebih dalam darah (hiperglikemia) yang tidak terkontrol
- jika anda mengalami peningkatan kadar garam (elektrolit) dalam darah (serum) yang terkandung dalam SmofKabiven Peripheral
- jika terdapat cairan dalam paru anda (udem paru akut)
- jika anda memiliki cairan berlebih dalam tubuh (hiperhidrasi)
- jika anda memiliki penyakit gagal jantung yang tidak diobati
- jika anda memiliki kelainan dalam sistem pembekuan darah (sindrom hemofagositosis)

DISETUJUI OLEH BPOM: 14/11/19

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- jika anda dalam kondisi yang tidak stabil, seperti paska luka berat, diabetes yang tidak terkontrol, serangan jantung akut, stroke, pembekuan darah, metabolik asidosis (gangguan yang menyebabkan asam berlebih dalam darah), infeksi serius (sepsis berat), koma, dan jika anda tidak memiliki cukup cairan dalam tubuh (dehidrasi hipotonik)

Berikan perhatian khusus pada SmofKabiven Peripheral :
Sampaikan pada dokter jika anda memiliki :
- gangguan ginjal
- diabetes mellitus
- pankreatitis (peradangan pada pankreas)
- gangguan fungsi hati
- hipotiroid (gondok)
- sepsis (infeksi berat)

Jika selama pemberian infus, anda mengalami demam, ruam, pembengkakan, sulit bernafas, menggigil, berkeringat, mual atau muntah, sampaikan segera pada tenaga ahli kesehatan karena gejala-gejala ini mungkin disebabkan oleh reaksi alergi atau anda diberikan obat berlebih.

Dokter anda mungkin perlu melakukan pemeriksaan darah untuk menilai fungsi hati dan penilaian lainnya.

SmofKabiven Peripheral tidak dapat digunakan untuk anak dan remaja usia kurang dari 18 tahun.

Penggunaan dengan obat lain :
Sampaikan kepada dokter anda jika anda sedang mengkonsumsi atau baru selesai mengkonsumsi obat-obatan lain, termasuk obat-obat yang diperoleh tanpa resep dokter.

Kehamilan dan menyusui :
Data penggunaan SmofKabiven Peripheral selama masa kehamilan atau menyusui masih kurang. Oleh karena itu, SmofKabiven Peripheral hanya diberikan pada ibu hamil atau menyusui jika dokter menilai penggunaannya memang dibutuhkan. Penggunaan SmofKabiven selama masa kehamilan dan menyusui dapat dipertimbangkan seperti yang disarankan dokter anda.

Mengemudi dan mengoperasikan mesin :
Tidak berhubungan selama obat diberikan di Rumah Sakit.

3. BAGAIMANA MENGGUNAKAN SMOFKABIVEN PERIPHERAL

Dokter akan memutuskan dosis untuk Anda secara individual tergantung dengan fungsi dan berat badan Anda. SmofKabiven Peripheral diberikan untuk Anda oleh tenaga ahli kesehatan.

Jika anda mendapatkan SmofKabiven Peripheral melebihi yang seharusnya anda terima
Hal ini tidak mungkin terjadi bahwa anda mendapatkan obat berlebih selama SmofKabiven Peripheral diberikan oleh tenaga ahli kesehatan.

4. EFEK SAMPING YANG MUNGKIN TERJADI

Sebagaimana semua obat, SmofKabiven Peripheral dapat menyebabkan efek samping, meskipun tidak semua orang mengalaminya.

Efek samping yang umum (lebih dari 1 pada 100 pasien) : Sedikit peningkatan suhu tubuh, peradangan pada tempat injeksi

Efek samping yang tidak umum (kurang dari 1 pada 100 pasien tapi lebih dari 1 pada 1.000 pasien) : kadar senyawa hati yang meningkat dalam darah (plasma), kurang nafsu makan, mual, muntah, menggigil, pusing dan sakit kepala.

Efek samping yang jarang (kurang dari 1 pada 1.000 pasien tapi lebih dari 1 pada 10.000 pasien): tekanan darah rendah atau tinggi, kesulitan bernafas, denyut jantung cepat (takikardia), reaksi hipersensitivitas yang memberikan gejala seperti pembengkakan, demam, penurunan tekanan darah, ruam kulit, bercak (merah-merah yang meluas), kemerahan, sakit kepala. Sensasi panas-dingin, nyeri pada leher, punggung, tulang dan payudara. Pucat, bibir dan kulit berwarna kebiruan (karena kekurangan oksigen dalam darah).

Jika salah satu efek samping terjadi, atau anda merasakan adanya efek samping yang tidak tercantum dalam leaflet ini, tolong sampaikan pada dokter atau apoteker anda.

5. BAGAIMANA MENYIMPAN SMOFKABIVEN PERIPHERAL

Jauhkan dari jangkauan dan penglihatan anak-anak. Simpan dalam kemasan. Jangan disimpan pada suhu diatas 25 ^{o}C. Jangan dibekukan.

Jangan digunakan setelah tanggal kadaluarsa, yaitu hari terakhir pada bulan yang tercantum pada karton dan label.

6. INFORMASI LEBIH LANJUT

Apa yang terkandung dalam SmofKabiven Peripheral

Komponen aktif dalam	**g/1000 ml**
Glukosa (monohidrat)	71
Alanin	4.4
Arginin	3.8
Glisin	3.5
Histidin	0.93
Isoleusin	1.6
Leusin	2.3
Lisin (asetat)	2.1
Methionin	1.3
Fenilalanin	1.6
Prolin	3.5
Serin	2.1
Taurin	0.32
Threonin	1.4
Triptofan	0.63
Tirosin	0.12

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Valin	2.0
Kalsium klorida (dihidrat)	0.18
Natrium gliserofosfat (hidrat)	1.3
Magnesium sulfat (heptahidrat)	0.38
Kalium klorida	1.4
Natrium asetat (trihidrat)	1.1
Zink sulfat (heptahidrat)	0.004
Minyak kedelai yang dimurnikan	8.5
Trigliserida rantai sedang	8.5
Minyak Zaitun yang dimurnikan	7.0
Minyak ikan, kaya akan omega-3	4.2

Komponen lain adalah gliserol, fosfolipid telur yang dimurnikan, semua rac-α-tocopherol, natrium hidroksida (digunakan untuk menyesuaikan pH), natrium oleat, asam asetat glasial (digunakan untuk menyesuaikan pH), dan aqua pro injeksi.

Apa tampilan SmofKabiven Peripheral dan isi kemasan
Larutan glukosa-asam amino yang jernih, tidak berwarna atau sedikit kuning dan bebas partikel. Emulsi lemak berwarna putih dan homogen.

Ukuran kemasan :
1 x 1448 ml
1 x 1904 ml

HARUS DENGAN RESEP DOKTER

Diproduksi oleh :
Fresenius Kabi AB, SE-751 Uppsala, Swedia.

Diimport oleh
PT Fresenius Kabi Combiphar
Bandung – Indonesia

No. Reg:

Informasi berikut ini hanya ditujukan untuk tim medis atau tenaga ahli kesehatan saja :
Peringatan dan Perhatian untuk Penggunaan

Untuk menghindari resiko yang berhubungan dengan kecepatan infus yang berlebih, disarankan untuk menggunakan infus kontinu dan terkontrol dengan baik. Jika memungkinkan dengan menggunakan pompa volumetrik.

Karena peningkatan resiko infeksi berhubungan dengan penggunaan vena perifer, tindakan pencegahan aseptis yang tepat harus dilakukan untuk menghindari kontaminasi terutama selama pemasangan kateter.

Kadar glukosa darah, elektrolit, dan osmolaritas serta keseimbangan cairan, status asam-basa, pemeriksaan enzim hati harus dipantau. Setiap tanda atau gejala reaksi anafilaksis (seperti demam, menggigil, ruam, atau sesak nafas) dapat mengarah pada gangguan langsung dari infus. SmofKabiven Peripheral tidak boleh diberikan di tempat infus yang sama dengan transfusi darah terkait dengan adanya risiko pseudoaglutinasi.

Thrombophlebitis mungkin terjadi jika vena perifer yang digunakan untuk pemasangan infus. Pemasangan kateter sebaiknya dievaluasi setiap hari terhadap gejala thrombophlebitis.

Cara pemberian
Hanya intravena, pemasangan infus ke vena sentral atau perifer.

Untuk menyediakan total parenteral nutrisi, mineral, vitamin, dan mungkin elektrolit (dengan mempertimbangkan jumlah elektrolit yang telah tersedia dalam SmofKabiven) dapat ditambahkan dalam SmofKabiven sesuai dengan kebutuhan pasien.

Kecepatan pemberian infus
Kecepatan pemberian infus maksimum untuk glukosa yaitu 0.25 g/kg bb/jam, untuk asam amino yaitu 0.1 g/kg bb/jam, dan untuk lemak 0.15 g/kg bb/jam.

Kecepatan pemberian infus tidak boleh melebihi 3.0 ml/kg bb/jam (sesuai dengan 0.21 g glukosa, 0.1 g asam amino, dan 0.08 g lemak/kg bb/jam). Waktu pemberian infus yang disarankan yaitu 14-24 jam.

Perhatian saat penggunaan
Jangan digunakan jika kemasan rusak
Gunakan hanya jika larutan asam amino dan glukosa jernih dan tidak berwarna, atau sedikit kuning dan emulsi lemak berwarna putih dan homogen. Isi dari 3 kantung chamber yang terpisah harus dicampur sebelum digunakan, dan sebelum penambahan apapun diberikan melalui sambungan tambahan.

Setelah pemisah segel dilepaskan, kantung harus dibalikkan beberapa kali untuk menjamin suatu campuran homogen, yang tidak menunjukkan adanya pemisahan fasa.

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Hanya digunakan untuk penggunaan sekali pakai. Sisa larutan yang tidak digunakan lagi setelah pemberian infus harus dibuang.

Kompatibilitas
Hanya obat atau larutan nutrisi yang memiliki kompatibilitas yang telah didokumentasikan yang boleh ditambahkan ke dalam SmofKabiven Peripheral. Kompatibilitas untuk zat tambahan yang berbeda dan waktu penyimpanan campuran yang berbeda dapat berbeda sesuai dengan permintaan.

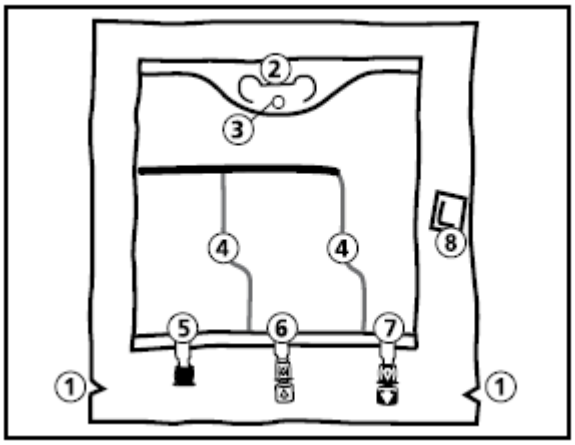
Penambahan harus dibuat secara aseptis.

Masa penyimpanan setelah pencampuran
Stabilitas fisika dan kimia dalam penggunaan campuran 3 kantung chamber telah terbukti selama 36 jam pada suhu 25 °C. Berdasarkan tinjauan mikrobiologi, produk ini harus segera digunakan. Jika tidak segera digunakan, masa penyimpanan penggunaan obat ini dan keadaan sebelum penggunaannya merupakan tanggungjawab yang memberikan produk ini dan normalnya tidak lebih dari 24 jam pada suhu 2-8°C.

Masa penyimpanan setelah pencampuran dengan zat tambahan
Berdasarkan tinjauan mikrobiologi, produk ini harus segera digunakan ketika zat tambahan telah dibuat. Jika tidak segera digunakan, masa penyimpanan penggunaan obat ini dan keadaan sebelum penggunaannya merupakan tanggungjawab yang memberikan produk ini. Waktu penyimpanan normalnya tidak lebih dari 24 jam pada suhu 2-8°C.

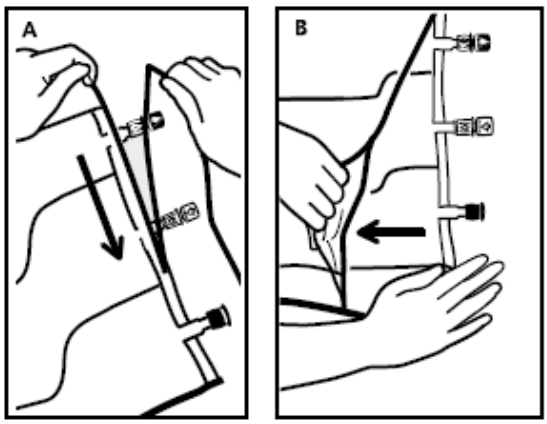
FRESENIUS KABI
INSTRUKSI PENGGUNAAN

Kemasan SMOFKabiven Peripheral



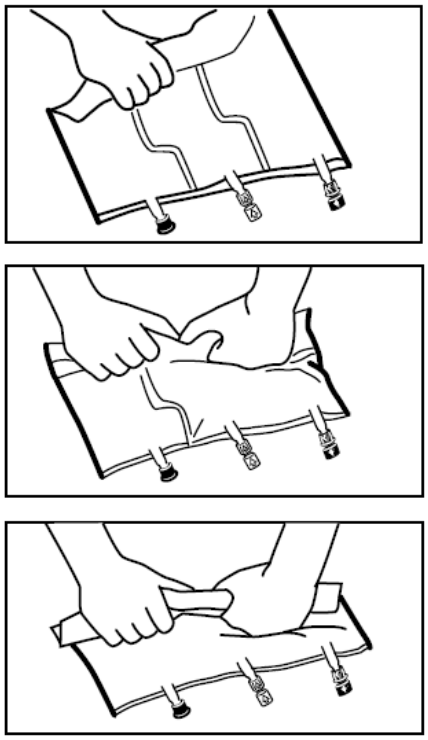
1. Gerigi pada sisi kantung
2. Pegangan infus
3. Lubang untuk menggantung kantung
4. Pemisah segel
5. Sambungan (port) tertutup (hanya digunakan selama produksi)
6. Sambungan (port) tambahan
7. Sambungan (port) untuk pemberian infus
8. Penyerap oksigen

1. Melepaskan kemasan pembungkus / kemasan luar



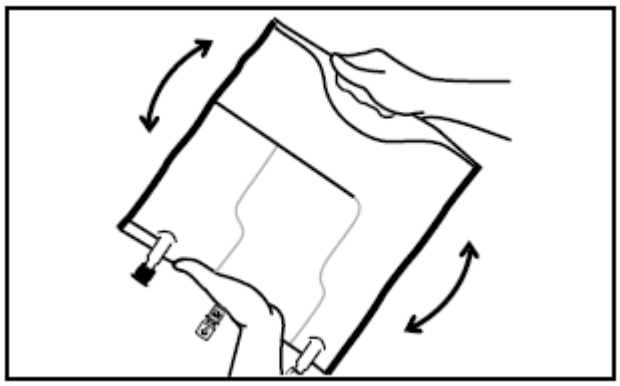
- Untuk melepaskan kemasan pembungkus / kemasan luar, pegang kantung secara horizontal dan sobek dari bagian gerigi hingga sepanjang tepi atas bagian port (A).
- Kemudian sobek di sepanjang sisinya, tarik bagian luar kantung dan buang bersama dengan penyerap oksigen (B).

2. Pencampuran

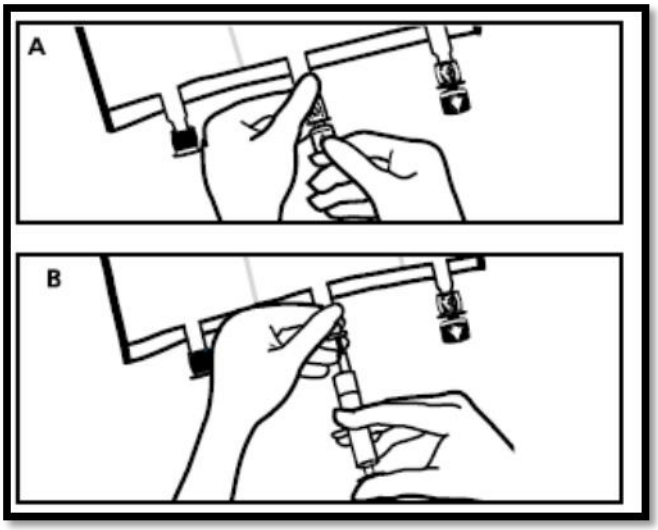


- Letakkan kantung pada permukaan yang rata
- Gulung kantung dengan erat dari sisi pegangan infus hingga bagian sambungan (port), pertama-tama dengan tangan kanan kemudian berikan tekanan konstan dengan tangan kiri hingga segel vertikal rusak. Kepingan segel vertikal juga dapat terbuka karena tekanan cairan atau dapat dibuka sebelum melepaskan bagian luar kantung.

  Harap diperhatikan : Larutan dapat bercampur dengan mudah meskipun segel horizontal tetap tertutup.



- Campurkan isi larutan pada tiga chamber dengan membalikkan kantung 3 kali hingga komponen tersebut tercampur merata.

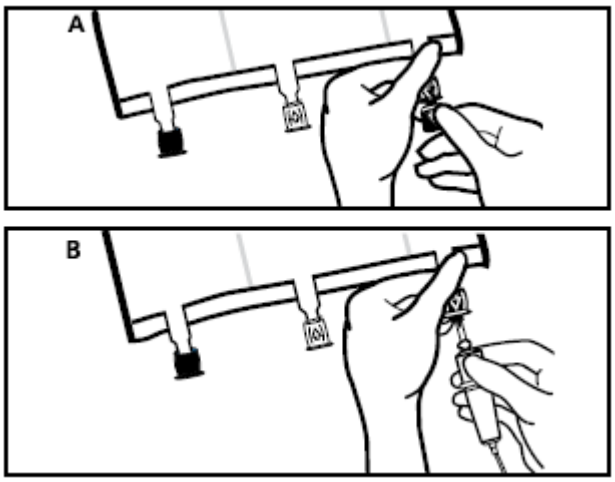


3. Penyiapan akhir

- Letakkan kantung pada permukaan yang rata lagi. Segera sebelum menyuntik zat tambahan lain, patahkan bendera anak panah dari sambungan (port) tambahan berwarna putih (A).

  Harap diperhatikan : selaput pada sambungan (port) tambahan bersifat steril.

- Pegang pangkalan dari sambungan (port) tambahan. Masukkan jarum, suntikkan zat tambahan (dengan kompatibilitas yang diketahui) melalui bagian tengah tempat penyuntikan (B).
- Campur terus tiap penambahan dengan membalikkan kantung 3 kali. Gunakan syringe dengan jarum ukuran 18-23 dan panjang maksimal 40 mm.



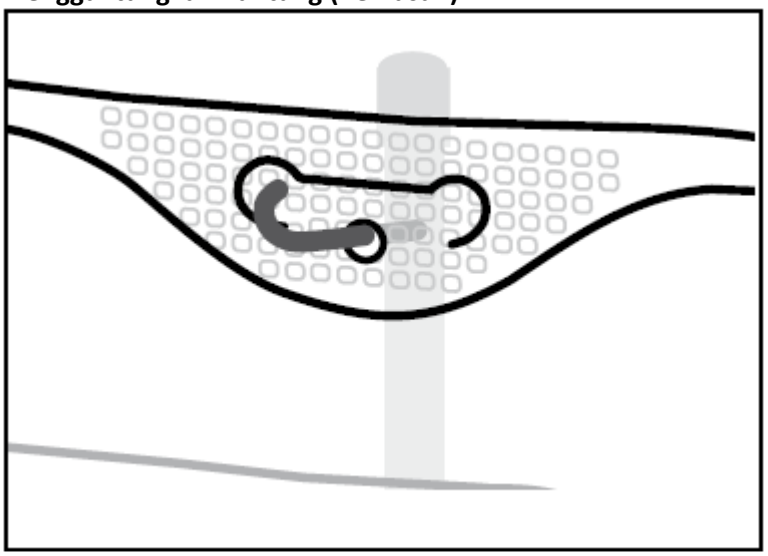
- Sebelum pemasangan infus set, segera patahkan bendera anak panah dari sambungan (port) tambahan berwarna putih (A).

  Harap diperhatikan : Selaput pada sambungan tempat infus bersifat steril

- Gunakan infus set yang tidak berlubang (non vented set) atau tutup saluran masuk udara jika menggunakan infus set yang berlubang (vented set).
- Pegang pangkal sambungan (port) infus
- Dorong spike melalui sambungan (port) infus. Spike harus sepenuhnya dimasukkan untuk menjamin penempatannya

  Harap diperhatikan : Bagian dalam sambungan (port) infus bersifat steril

4. Menggantungkan Kantung (Kemasan)



- Gantungkan kemasan pada lubang yang terdapat dibawah bagian pegangan kemasan.