



emulsion), for intravenous use

(amino acids, electrolytes, dextrose, and lipid injectable emulsion), for intravenous use

Kabiven and Perikabiven

Composition Chart*

Kabiven (central PN)				
Volume (mL)	1026	1540	2053	2566
Amino Acids (g)	34	51	68	85
Nitrogen (g)	5.4	8.1	10.8	13.5
Dextrose (g)	110	165	220	275
Lipids (g)	40	60	80	100
Total kcal	910	1365	1820	2275
Electrolytes [†]				
Sodium (mEq)	32	48	64	80
Potassium (mEq)	24	35	47	59
Magnesium (mEq)	8	12	16	20
Acetate (mEq)‡	39	59	78	98
Chloride (mEq)§	46	69	92	115
Sulfate (mEq)	8	12	16	20
Calcium (mEq)	4	6	8	10
Phosphorus (mmol)¶	10	15	20	25
Osmolarity (mOsm/L)	1060	1060	1060	1060

Perikabiven (peripheral or central PN)				
1440	1920			
34	45			
5.4	7.2			
107	143			
51	68			
1010	1346			
32	42			
24	33			
8	11			
39	52			
46	61			
8	11			
4	5			
11	14			
750	750			

^{*} Calculations in this table are per bag and differ from Table 2 in the Kabiven/Perikabiven Prescribing Information that are calculated per 1000 mL or 100 mL.

[†] Provided as sodium acetate, potassium chloride, sodium glycerophosphate, magnesium sulfate, and calcium chloride.

[‡] Derived from sodium acetate and glacial acetic acid (for pH adjustment).

[§] Contributed by calcium chloride, lysine hydrochloride, and potassium chloride.

[¶] Contributed by sodium glycerophosphate and phospholipids.

INDICATIONS AND USAGE

KABIVEN and PERIKABIVEN are each indicated as a source of calories, protein, electrolytes, and essential fatty acids for adult patients requiring parenteral nutrition when oral or enteral nutrition is not possible, insufficient, or contraindicated. KABIVEN and PERIKABIVEN may be used to prevent essential fatty acid deficiency or treat negative nitrogen balance in adult patients.

Limitations of Use

Neither KABIVEN nor PERIKABIVEN is recommended for use in pediatric patients <2 years including preterm infants because the fixed content of the formulation does not meet nutritional requirements in this age group.

IMPORTANT SAFETY INFORMATION

KABIVEN is indicated for intravenous infusion into a **central vein**. It is recommended to mix the contents thoroughly by inverting the bags upside down to ensure a homogenous admixture. Ensure the vertical seals between chambers are broken and the contents of all three chambers for KABIVEN and PERIKABIVEN are mixed together prior to infusion. The dosage of KABIVEN and PERIKABIVEN should be individualized based on the patient's clinical condition (ability to adequately metabolize amino acids, dextrose, and lipids), body weight and nutritional/fluid requirements, as well as additional energy given orally/enterally to the patient. Prior to administration of KABIVEN and PERIKABIVEN, correct severe fluid, electrolyte, and acid-base disorders. Before starting the infusion, obtain serum triglyceride levels to establish the baseline value. Do not exceed the recommended maximum infusion rate of 2.6 mL/kg/hour for KABIVEN and 3.7 mL/kg/hour for PERIKABIVEN.

KABIVEN and PERIKABIVEN are contraindicated in:

- Concomitant treatment with ceftriaxone in neonates (28 days of age or younger)
- Known hypersensitivity to egg, soybean, peanut, or any of the active or inactive ingredients
- Severe disorders of lipid metabolism characterized by hypertriglyceridemia (with serum triglyceride concentration >1,000 mg/dL)
- · Inborn errors of amino acid metabolism
- Cardiopulmonary instability
- Hemophagocytic syndrome

<u>Clinical Decompensation with Rapid Infusion of Lipid Injectable Emulsions in Neonates and Infants</u>: Acute respiratory distress, metabolic acidosis, and death after rapid infusion of intravenous lipid emulsions have been reported.

<u>Parenteral Nutrition-Associated Liver Disease</u>: Increased risk in patients who receive parenteral nutrition for greater than 2 weeks. Monitor liver tests; if abnormalities occur, consider discontinuation or dosage reduction.

<u>Pulmonary Embolism and Respiratory Distress due to Pulmonary Vascular Precipitates</u>: If signs of pulmonary distress occur, stop the infusion and initiate a medical evaluation.

<u>Hypersensitivity Reactions</u>: Monitor for signs or symptoms and discontinue infusion if reactions occur.

Precipitation with Ceftriaxone: Do not administer ceftriaxone simultaneously with KABIVEN or PERIKABIVEN via a Y-site.

Infection, Fat Overload, Hyperglycemia, and Refeeding Complications: Monitor for signs and symptoms; monitor laboratory parameters.

The most common adverse reactions for KABIVEN (\geq 3%) are nausea, pyrexia, hypertension, vomiting, decreased hemoglobin, decreased total protein, hypokalemia, decreased potassium, and increased gamma glutamyltransferase. The most common adverse reactions for PERIKABIVEN (\geq 3%) are hyperglycemia, hypokalemia, pyrexia, and increased blood triglycerides.

To report SUSPECTED ADVERSE REACTIONS, contact Fresenius Kabi USA, LLC at 1-800-551-7176, option 5, or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

<u>Coumarin and Coumarin Derivatives, Including Warfarin</u>: Anticoagulant activity may be counteracted; monitor laboratory parameters.

This Important Safety Information does not include all the information needed to use KABIVEN and PERIKABIVEN safely and effectively. Please see full prescribing information for KABIVEN and PERIKABIVEN (amino acids, electrolytes, dextrose, and lipid injectable emulsion), for intravenous use at www.FreseniusKabiNutrition.com/KabivenPI and www.FreseniusKabiNutrition.com/PerikabivenPI.

To order: **1-888-386-1300**Medical Information phone: **1-800-551-7176** (option 4)

www.FreseniusKabiNutrition.com/products/kabiven-perikabiven

Medical Information email: Nutrition.MedInfo.USA@fresenius-kabi.com
Information on coding and billing:
www.FreseniusKabiNutrition.com/billing-coding/

