Package leaflet: Information for the user

Kabiven Peripheral, emulsion for infusion

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. WHAT KABIVEN IS AND WHAT IT IS USED FOR

Kabiven comes in a three-chamber bag in an overpouch.
Kabiven contains the following medicines: amino acids (components used to build proteins), fat, glucose and electrolyte solutions. It provides energy (as sugar and fat) and amino acids into your bloodstream when you cannot eat normally.

It is used as part of a balanced intravenous diet, together with salts, trace elements and vitamins which together provide your complete nutritional needs.

2. WHAT YOU NEED TO KNOW BEFORE YOU ARE GIVEN KABIVEN

You should not receive Kabiven:

- if you are **allergic** to any of the active substances or any of the other ingredients of this medicine (listen in section 6).
- if you are allergic to products containing **egg, soya or peanut**
- if you have **too much fatty substances** (like cholesterol) in your blood
- if you have seriously reduced **liver** function
- if you suffer from **acute shock** (resulting from heavy blood loss or allergic reaction)
- if you have a **defect in your blood clotting system** (haemophagocytotic syndrome) or if your **blood is not clotting properly**
- if you have a condition where your body has problems using proteins or amino acids
- if you have severe problems with your **kidneys**
- if you have hyperglycaemia (**too much sugar in your blood**) where the administration of more than 6 units of insulin per hour is required
- if you have **raised levels of electrolytes** (salts) in your blood
- if you have **metabolic acidosis** (the acid levels of your body fluids and tissues become too high)
- if you have **too much fluid** in your body - hyperhydration
- if you have **fluid on your lungs** (acute pulmonary oedema)
- if you are **dehydrated** with low levels of salts

- if you have **heart problems**
- if you are in a **coma**
- if you have **severe sepsis** (a condition in which your body is fighting a severe infection)

Warning and precautions

Talk to your doctor before you are given Kabiven if you have:

- reduced **liver** function
- untreated **diabetes**
- a condition where your body has problems using fat properly
- **kidney** problems
- any **pancreas** problems
- **thyroid** problems - hypothyroidism
- **sepsis** (a condition in which your body is fighting an infection)
- your body has problems eliminating electrolytes
- a condition where there is **not enough oxygen** in your body cells
- increased serum osmolarity

If during the infusion you get a fever, rash, shiver or have difficulty breathing tell the health care professional immediately. These symptoms might be caused by an allergic reaction or show that you have been given too much of the medicine (see section 4).

This medicine may affect the results of other tests you may have. It is important to tell any doctor doing tests that you are using Kabiven Peripheral.

Your doctor may want to do regular blood tests to make sure that the treatment with Kabiven Peripheral is working correctly.

Children

Kabiven will not be given to newborns or children under two years of age.

Other medicines and Kabiven

Tell your doctor or pharmacist if you are using or have recent used or might use any other medicines.

- Inform your doctor if you are taking
  a drug known as heparin which is used to prevent the formation and aid in the dispersion of blood clots
- warfarin, because Vitamin K1, which is contained in soybean oil, could affect the blood clotting ability
- Insulin for the treatment of diabetes

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before you are given this medicine.
The safety of using Kabiven while pregnant or breast-feeding has not
been looked into. If feeding directly into your vein (parenteral nutrition) becomes necessary during pregnancy or breast-feeding, your doctor will give you Kabiven only after careful consideration.

Driving and using machines

Kabiven is not expected to affect your ability to drive and use machines.

3. HOW YOU ARE GIVEN KABIVEN

You will receive your medicine by infusion only into a central vein. The dose of Kabiven and which bag size is used depends on your bodyweight in kilograms and your body's ability to use fat and sugar. Kabiven will be infused slowly over a period of 12-24 hours. Your doctor will decide on the correct dose for you or your child to receive. You may be monitored during your treatment.

Children
Kabiven is not suitable for use in new-borns or children under two years of age.

If you are given more Kabiven than you should
It is very unlikely that you will receive more infusion than you should as your doctor or nurse will monitor you during the treatment. The effects of an overdose may include nausea, vomiting, sweating and fluid retention. Hyperglycaemia (too much sugar in your blood) and electrolyte disturbances have also been reported. In case of overdose there is a risk of taking in too much fat. This is called 'fat overload syndrome'. See section 4 "Possible side effects" for more information. If you experience any of the symptoms described above or believe that you have received too much Kabiven inform your doctor or nurse immediately. The infusion may either be stopped immediately or continued with a reduced dosage. These symptoms will usually disappear on reducing the rate or stopping the infusion.

If you have any further questions on the use of this product, ask your doctor, nurse or pharmacist

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Kabiven may cause an allergic reaction (very rare, may affect up to 1 in 10, 000 people). Tell your doctor immediately if:
- a bumpy and itchy rash appears on your body
- you have very high temperature
- you have difficulties breathing

Other side effects include:

Common side effects (may affect up to 1 in 100 people)
- a slightly raised body temperature

Uncommon side effects (may affect up to 1 in 100 people)
- chills
- tiredness
- stomach pain
- headache
- feeling sick or being sick
- increase of liver enzymes. Your doctor will tell you if this happens.

Very rare side effects (may affect up to 1 in 10, 000 people)
- high or low blood pressure
- difficulty in breathing

- prolonged, painful erections in men
- problems with your blood

Fat overload syndrome
This might happen when your body has problems using fat, because of having too much Kabiven. It may also happen because of a sudden change in your condition (such as kidney problems or infection). Possible symptoms are fever, increased levels of fat in your blood, your cells and your tissues, disorders in various organs and coma. All these symptoms will usually disappear if the infusion is discontinued.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side affects you can help provide more information on the safety of this medicine.

UK: Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

Ireland: HPRA Pharmacovigilance

Website: www.hpra.ie

By reporting side affects you can help provide more information on the safety of this medicine

The following information is intended for healthcare professionals only:

Warnings and precautions for use
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.

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 especially during catheter insertion.

Serum glucose, electrolytes and osmolarity as well as fluid balance, acid-base status and liver and enzyme tests should be monitored.

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

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

Method of administration

Intravenous use, infusion into a central vein.

To provide total parenteral nutrition, trace elements, vitamins and possibly electrolytes (taking into account the electrolytes already present in Kabiven) should be added to Kabiven according to the patients need.

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 2.6 ml/kg body weight/hour
(Corresponding to 0.25 g glucose, 0.09 g amino acid and 0.1 g fat/kg body weight). The recommended infusion period is 12-24 hours.

Precautions for disposal

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 fat 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 three times to ensure a homogenous mixture which does not show any evidence of phase separation.

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

Compatibility

Compatibility data are available with the named branded products Dipeptiven, Addamel N/Addaven, Glycophos, Addiphos, Vitalipid N Adult/Infant and Soluvit N in defined amounts and generics of electrolytes in defined concentrations. When making electrolyte additions, the amounts already present in the bag should be taken into account to meet the clinical needs of the patient. Generated data supports additions to the activated bag according to the summary table below

	Units	**Maximal total contents**		
Kabiven Peripheral bag size	ml	1440	1920	2400
Additive		**Volume**		
Dipeptiven	ml	0 - 300	0 - 300	0 - 300
Addaven/Addamel N	ml	0 - 10	0 - 10	0 - 10
Soluvit N	vial	0 - 1	0 - 1	0 - 1
Vitalipid N Adult/Infant	ml	0 - 10	0 - 10	0 - 10
Electrolyte limits[1]		**Amount per bag**		
Sodium	mmol	≤ 216	≤ 288	≤ 360
Potassium	mmol	≤ 216	≤ 288	≤ 360
Calcium	mmol	≤ 7.2	≤ 9.6	≤ 12
Magnesium	mmol	≤ 7.2	≤ 9.6	≤ 12

	Units	Maximal total contents		
Kabiven Peripheral bag size	ml	1440	1920	2400
Phosphate inorganic (Addiphos) OR Phosphate organic	mmol	≤ 22	≤ 29	≤ 36

[1.] *includes amounts from all products*

Note: This table is intended to indicate compatibility. It is not a dosing guideline.
For branded products, before prescribing refer to national approved prescribing information.

Compatibility with further additives and the storage time of different admixtures will be available upon request.

Additions should be made aseptically.

Any unused medicinal product or waste material should be disposed in accordance with local requirement.

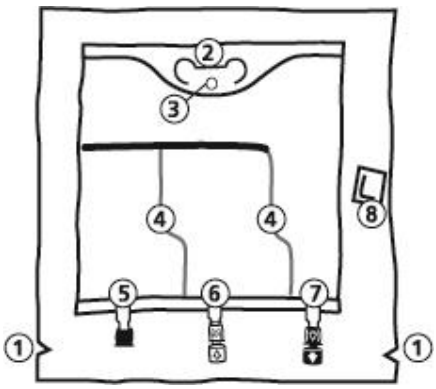
Shelf-life
Shelf-life after mixing the chambers of the bag
After breaking the seals, chemical and physical in-use stability of the mixed three chamber bags has been demonstrated for 48at 20-25°C including duration of administration. From a microbiological point of view the product should be used immediately. 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, unless mixing has taken place in controlled and validated aseptic conditions

Shelf-life after mixing with additives
After opening the peelable seals and mixing of the three solutions, additions can be made via additive port. Physico-chemical in-use stability of the mixed three chamber bag with additives has been demonstrated for up to 8 days, i.e., 6 days at 2-8°C followed by 48 hours at 20-25°C, including duration of administration. 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. , unless addition of supplements has taken place in controlled and validated aseptic conditions

Kabiven Peripheral

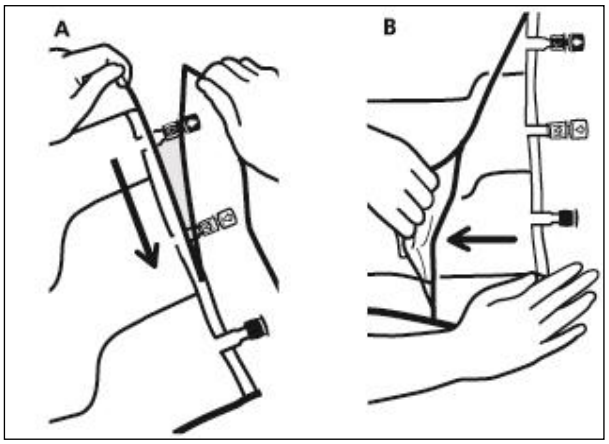
Instructions for use

The bag



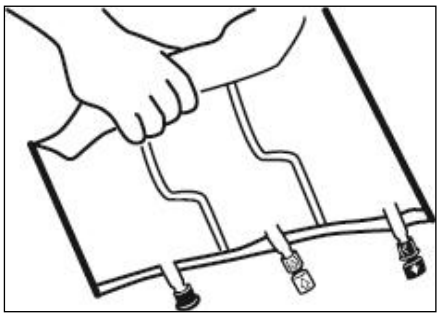
1. Notches in the overpouch
2. Handle
3. Hole for hanging the bag
4. Peelable seals
5. Blind port (only used during Manufacturing)
6. Additive port
7. Infusion port
8. Oxygen absorber

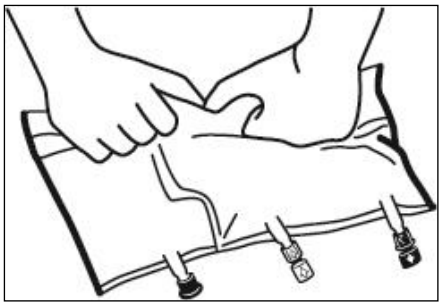
1. Removal of overpouch

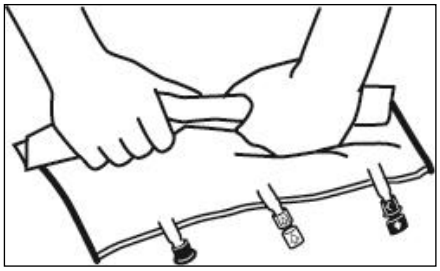


- To remove overpouch, hold the bag horizontally and tear from the notch close to the ports along the upper edge (A).
- Then simply tear the long side, pull off the overpouch and discard it along with the oxygen absorber (B).

2. Mixing

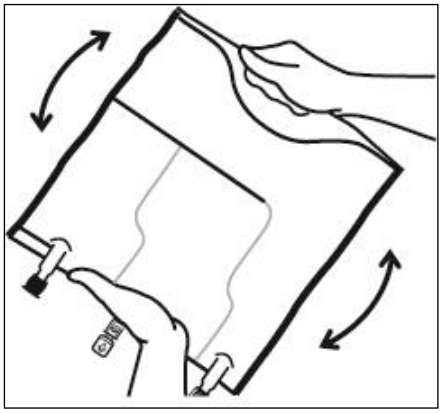






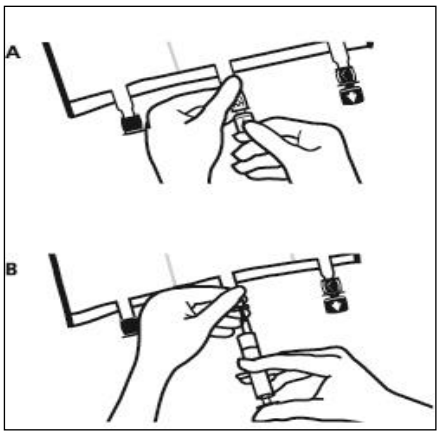
- Place the bag on a flat surface.
- Roll up the bag tightly from the handle side towards the ports, firstly with the right hand and then applying a constant pressure with the left hand until the vertical seals are broken. The vertical peel seals open due to the pressure of the fluid. The peel seals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

  Please note: The liquids mix easily although the horizontal seal remains closed.

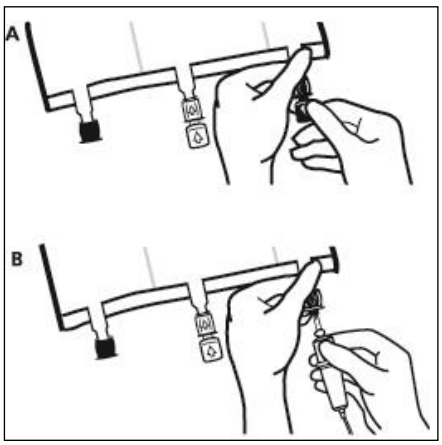


- Mix the contents of the three chambers by inverting the bag three times until the components are thoroughly mixed.

3. Finalising the preparation:

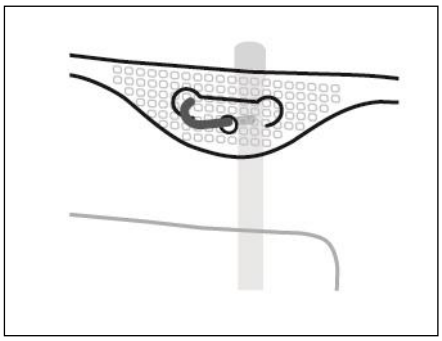


- Place the bag on a flat surface again. Shortly before injecting the additives, break off the tamper-evident arrow flag from the white additive port (A).
  Please note: The membrane in the additive port is sterile.
- Hold the base of the additive port. Insert the needle, inject the additives (with known 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. Hooking up the bag



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

5. HOW TO STORE KABIVEN

Keep this medicine out of the sight and reach of children.
Your doctor and hospital pharmacist are responsible for the correct storage, use and disposal of Kabiven. Do not store above 25° C. Do not freeze and always keep the container in the outer container. The emulsion must not be used after the expiry date shown on the label. The expiry date refers to the last day of that month.
Do not use if the bag is leaking
For single use only. Any mixture remaining after infusion must be disposed of using the approved hospital procedures.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Kabiven contains
Kabiven is available in a three-chamber bag system. Each bag contains the following different volumes depending on the four pack sizes:

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

- The active substances are

Purified soybean oil	85 g	68 g	51 g
Glucose monohydrate	178 g	143 g	107 g
Corresponding to Glucose (anhydrous)	162 g	130 g	97 g
Alanine	8.0 g	6.4 g	4.8 g
Arginine	5.6 g	4.5 g	3.4 g
Aspartic acid	1.7 g	1.4 g	1.0 g
Glutamic acid	2.8 g	2.2 g	1.7 g
Glycine	4.0 g	3.2 g	2.4 g
Histidine	3.4 g	2.7 g	2.0 g
Isoleucine	2.8 g	2.2 g	1.7 g

Leucine	4.0 g	3.2 g	2.4 g
Lysine hydrochloride	5.6 g	4.5 g	3.4 g
Corresponding to Lysine	4.5.g	3.6 g	2.7 g
Methionine	2.8 g	2.2 g	1.7 g
Phenylalanine	4.0 g	3.2 g	2.4 g
Proline	3.4 g	2.7 g	2.0 g
Serine	2.2 g	1.8 g	1.4 g
Threonine	2.8 g	2.2 g	1.7 g
Tryptophan	0.95 g	0.76 g	0.57 g
Tyrosine	0.12 g	0.092 g	0.069 g
Valine	3.6 g	2.9 g	2.2 g
Calcium chloride 2 H_2O	0.49 g	0.39 g	0.29 g
Corresponding to Calcium chloride	0.37 g	0.30 g	0.22 g
Sodium glycerophosphate (anhydrous)	2.5 g	2.0 g	1.5 g
Magnesium sulphate 7 H_2O	1.6 g	1.3 g	0.99 g
Corresponding to Magnesium sulphate	0.80 g	0.64 g	0.48 g
Potassium chloride	3.0 g	2.4 g	1.8 g
Sodium acetate 3 H_2O	4.1 g	3.3 g	2.5 g
Corresponding to Sodium acetate	2.4 g	2.0 g	1.5 g

- The other ingredients are
  Purified egg phospholipids,
  Glycerol,
  Sodium hydroxide,
  Glacial acetic acid
  Water for injections

What Kabiven Peripheral looks like and contents of the pack
Glucose and amino acid solutions are clear and colourless or slightly yellow and the fat emulsion is white. Kabiven Peripheral consists of a three-chamber bag and an over pouch. An oxygen absorber is placed between the inner bag and the over pouch, which should be discarded before use. The inner bag is separated into three chambers by peelable seals. The contents of the three chambers have to be mixed before use, by opening the peelable seals.

Pack sizes:
1 x 1440 ml, 4 x 1440 ml
1 x 1920 ml, 4 x 1920 ml (Biofine)
1 x 2400 ml, 3 x 2400 ml (Biofine)

Not all pack sizes may be marketed.

Marketing Authorisation Holder
MAH for UK:
Fresenius Kabi Ltd.,
Cestrian Court, Eastgate Way,
Manor Park, Runcorn, Cheshire,
WA7 1NT, U.K.

MAH for IRL:
Fresenius Kabi Deutschland GmbH
Else-Kröner-Straße 1,
61352 Bad Homburg

v.d.Höhe
Germany
Manufacturer
Fresenius Kabi AB,
SE-751 74 Uppsala, Sweden.
Fresenius Kabi Austria GmbH,
Hafnerstrasse 36,
AT-8055 Graz, Austria.

This medicinal product is authorised in the Member States of the EEA under the following names:

Belgium	Kabiven Peri
Denmark	Kabiven Perifer
Finland	Kabiven Perifer
France	Perikabiven
Germany	Kabiven Peripher
Greece	Kabiven Peripheral
Iceland	Kabiven Perifer
Ireland	Kabiven Peripheral
Italy	Periven
Netherlands	Kabiven Perifeer
Norway	Kabiven Perifer
Portugal	Kabiven Peripheral
Spain	Kabiven Periférico
Sweden	Kabiven Perifer
United Kingdom	Kabiven Peripheral

This leaflet was last revised in December 2023