Package leaflet: Information for the user

StructoKabiven emulsion for infusion

Read all of this leaflet carefully before you start using 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 StructoKabiven is and what it is used for

StructoKabiven is an emulsion for infusion given into your blood by a drip (intravenous infusion).
The product contains amino acids (components used to build proteins), glucose, fat and salts in a plastic bag.

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 StructoKabiven

You should not be given StructoKabiven:
- if you are allergic to any of the active substances or any of the other ingredients of this medicine (listed in section 6).
- if you are allergic to egg, peanut or soya. The product contains soyabean oil
- if you have too much fat in the blood (hyperlipidaemia)
- if you have serious liver disease
- if you have blood clotting problems (coagulation disorders or haemophagocytotic syndrome)
- if you your body has problems using amino acids
- if you have serious kidney disease without access to dialysis
- if you are in acute shock
- if you have too much sugar in your blood (hyperglycaemia)
- if you have high blood (serum) levels of the salts (electrolytes) included in StructoKabiven
- if you have fluid in the lungs (acute pulmonary oedema)
- if you have too much body fluid (hyperhydrated)
- if you have heart failure that is not treated
- if you don’t have enough body fluid (hypotonic dehydration).
- if you are in an unstable condition, such as after serious trauma, uncontrolled diabetes, acute heart attack, metabolic acidosis (a disturbance resulting in too much acid in the blood), serious infection (severe sepsis) and coma

Warnings and precautions
Talk to your doctor before you are given StructoKabiven if you have:
- kidney problems
- diabetes mellitus
- pancreatitis (inflammation of the pancreas)
- liver problems
- hypothyroidism (thyroid problems)
- sepsis (serious infection)

Your doctor may want to do regular blood tests to make sure your body is using StructoKabiven correctly.

Children
StructoKabiven is not meant for newborn babies or children younger than 2 years of age. At the moment, there is no experience of the use of StructoKabiven in children from 2 to 11 years old.

Other medicines and StructoKabiven
Tell your doctor or pharmacist if you are using, have recently 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
- anticoagulating agents (coumarin derivates) as Vitamin K_1, 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.

StructoKabiven should be used during pregnancy only after special consideration.
Women treated with StructoKabiven should not breast-feed

Driving and using machines
No effects on the ability to drive and operate machines are to be expected.

StructoKabiven contains soya-bean oil
This medicinal product contains soya-bean oil, which may rarely cause severe allergic reactions. Cross allergic reaction has been observed between soya-bean and peanut.

3. How you are given StructoKabiven

Your doctor will decide on the dose for you individually depending on your body weight and function.
StructoKabiven will be given to you by a health professional. You will receive your medicine by infusion only into a central vein. You may be monitored during your treatment.

If you are given more StructoKabiven 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, fever, vomiting, shivering, 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 StructoKabiven 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 or nurse.

4. Possible side effects

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

Tell the health care professional immediately if you get fever, rash, swelling of tongue or throat, difficulty in breathing, chills, sweating, nausea or vomiting during the infusion. These symptoms might be caused by an allergic reaction to the medicine.

Other side effects include:

Uncommon (may affect up to 1 in 100 people): high blood (plasma) levels of compounds from the liver, nausea, headache, rise in body temperature.

Rare (may affect up to 1 in 1,000 people): fast heart beat (tachycardia), high blood pressure

Very rare (may affect up to 1 in 10,000 people): difficulty in breathing, diarrhoea, rash, back pain, dizziness

Fat overload syndrome

This might happen when your body has problems using fat, because of having too much StructoKabiven. 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.

Excess of amino acids

This might happen when the amino acid level is exceeded when the infusion rate is increased. Possible symptoms are nausea, vomiting, shivering, sweating and a rise in your body temperature. If you have kidney problems your doctor may want to perform blood tests to measure the amount of nitrogen containing substances in your blood.

Excess glucose

This may occur when your body has problems removing glucose from your body as this will result in too much sugar in your blood (hyperglycaemia).

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 effects you can help provide more information on the safety of this medicine.

[To be completed nationally]

5. How to store StructoKabiven

- Keep this medicine out of the sight and reach of children.
- Do not store above 25°C.
- Do not freeze.
- Keep the container in the overpouch
- Do not use StructoKabiven after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

▪ Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Content of the pack and other information

What StructoKabiven contains

	986 ml	**1477 ml**	**1970 ml**	**Per 1000 ml**
Amino acid solution with electrolytes	500 ml	750 ml	1000 ml	508 ml
Glucose 42%	298 ml	446 ml	595 ml	302 ml
Fat emulsion	188 ml	281 ml	375 ml	190 ml

This corresponds to the following total compositions:

– The active substances are

	986 ml	**1477ml**	**1970 ml**	**Per 1000 ml**
Purified structured triglyceride	38 g	56 g	75 g	38.5 g
Glucose (as monohydrate)	125 g	187 g	250 g	127 g
Alanine	7.0 g	10.5 g	14.0 g	7.1 g
Arginine	6.0 g	9.0 g	12.0 g	6.1 g
Glycine	5.5 g	8.2 g	11.0 g	5.6 g
Histidine	1.5 g	2.2 g	3.0 g	1.5 g
Isoleucine	2.5 g	3.8 g	5.0 g	2.5 g
Leucine	3.7 g	5.6 g	7.4 g	3.8 g
Lysine (as acetate)	3.3 g	5.0 g	6.6 g	3.4 g
Methionine	2.2 g	3.2 g	4.3 g	2.2 g
Phenylalanine	2.6 g	3.8 g	5.1 g	2.6 g
Proline	5.6 g	8.4 g	11.2 g	5.7 g
Serine	3.2 g	4.9 g	6.5 g	3.3 g
Taurine	0.50 g	0.75 g	1.0 g	0.5 g
Threonine	2.2 g	3.3 g	4.4 g	2.2 g
Tryptophan	1.0 g	1.5 g	2.0 g	1.0 g
Tyrosine	0.20 g	0.30 g	0.40 g	0.20 g
Valine	3.1 g	4.6 g	6.2 g	3.1 g
Calcium chloride (as Calcium chloride dihydrate)	0.28 g	0.42 g	0.56 g	0.28 g
Sodium glycerophosphate (as hydrate)	2.1 g	3.1 g	4.2 g	2.13 g
Magnesium sulphate (as Magnesium sulphate heptahydrate)	0.60 g	0.90 g	1.2 g	0.61 g
Potassium chloride	2.2 g	3.4 g	4.5 g	2.3 g
Sodium acetate (as Sodium acetate trihydrate)	1.7 g	2.6 g	3.4 g	1.7 g
Zinc sulphate *(*as Zinc sulphate heptahydrate)	0.0065 g	0.0097 g	0.013 g	0.0066 g

– The other ingredients are
Glycerol
Purified egg phospholipids

Sodium hydroxide (pH-adjustment)
Acetic acid glacial (pH-adjustment)
Hydrochloric acid (pH-adjustment)
Water for injections

What StructoKabiven looks like and contents of the pack
Glucose- and aminoacid solutions are clear, colourless or slightly yellow and free from particles. The fat emulsion is white and homogenous.

Pack sizes:
1 x 986 ml, 4 x 986 ml
1 x1477 ml, 4 x 1477 ml
1 x 1970 ml, 2 x 1970 ml (Excel), 4 x 1970 (Biofine)

Not all pack sizes may be marketed

Marketing Authorisation Holder and Manufacturer

Marketing authorisation holder:
To be completed nationally

Manufacturer:
Fresenius Kabi AB, 751 74 Uppsala, Sweden
Fresenius Kabi GmbH, Graz, Austria

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

Austria	StructoKabiven
Belgium	StructoKabiven
Czech Republic	StructoKabiven
Denmark	StructoKabiven
Finland	StructoKabiven
France	StructoKabiven E
Germany	StructoKabiven
Greece	StructoKabiven
Iceland	StructoKabiven
Ireland	StructoKabiven
Italy	Krinuven
Luxemburg	StructoKabiven
Netherlands	StructoKabiven
Norway	StructoKabiven
Portugal	StructoKabiven
Slovakia	StructoKabiven
Slovenia	StructoKabiven
Spain	StructoKabiven
Sweden	StructoKabiven
United Kingdom	StructoKabiven

This leaflet was last revised in 2015-05-04.

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The following information is intended for health care 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 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.

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

StructoKabiven 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 and vitamins should be added to StructoKabiven according to the patients need.

Infusion rate

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

The infusion rate should not exceed 2.0 ml/kg/hour (corresponding to 0.25 g glucose, 0.10 g amino acid, and 0.08 g fat/kghour). The recommended infusion period is 14-24 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 on a number of occasions 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
Only medicinal or nutrition solutions for which compatibility has been documented may be added to StructoKabiven. Compatibility for different additives and the storage time of the different admixtures will be available upon request.

Addition should be made aseptically.

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.

StructoKabiven Instructions for use

The bag

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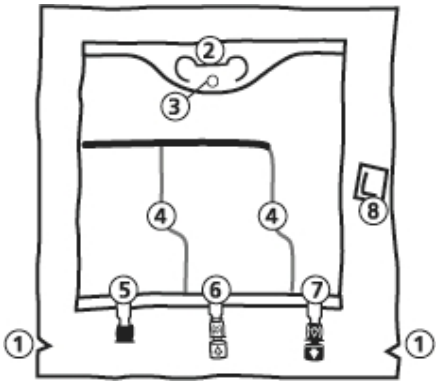

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1. Notches in the overpouch
2. Handle
3. Hole for hanging the bag
4. Peelable seals
5. Blind port (only used during Manufacturing)
6. Additive port
7. Infusion port
8. Oxygen absorber

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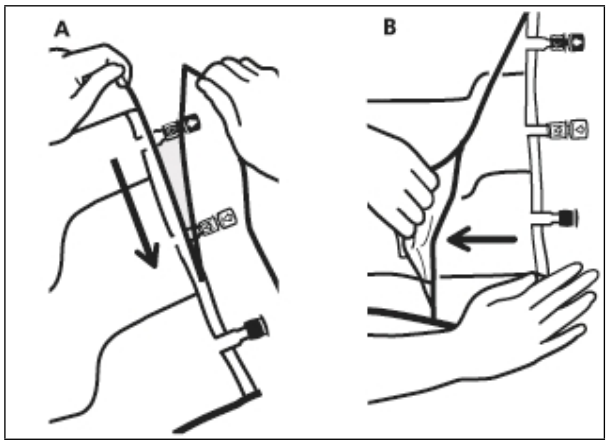
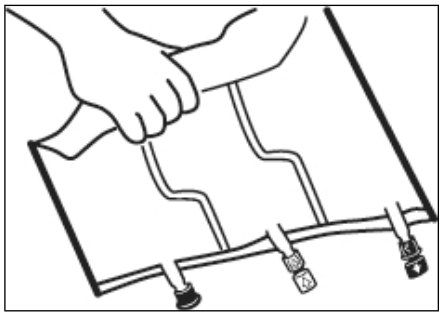
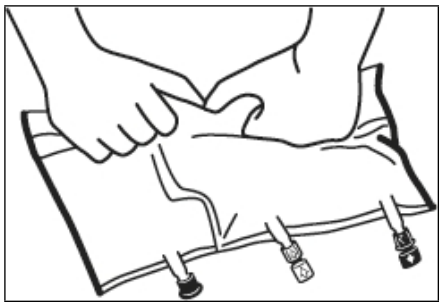
1. Removal of overpouch

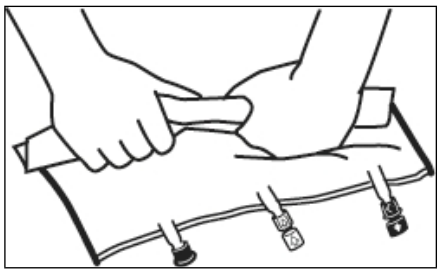


- To remove overpouch, hold the bag horizontally and tear from the notch close to the ports along the upper edge (A).
- Then simply tear the long side, pull off the overpouch and discard it along with the oxygen absorber (B).

2. Mixing

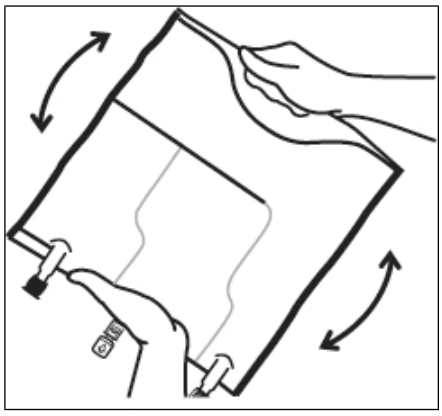






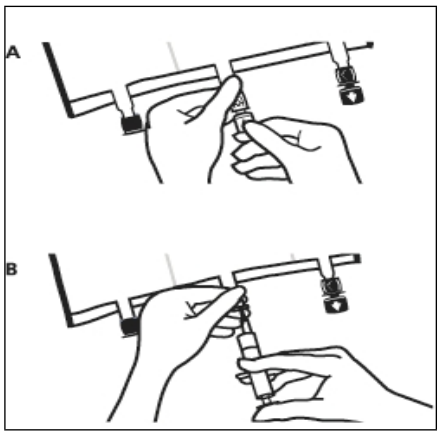
- Place the bag on a flat surface.
- Roll up the bag tightly from the handle side towards the ports, firstly with the right hand and then applying a constant pressure with the left hand until the vertical seals are broken. The vertical peel seals open due to the pressure of the fl uid. The peel seals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

Please note: The horizontal seal should not be broken. 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.

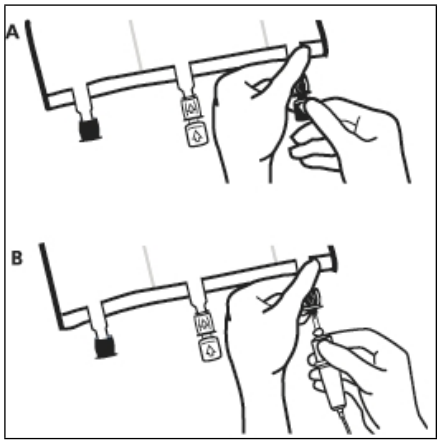
3. Finalising the preparation:



- 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.



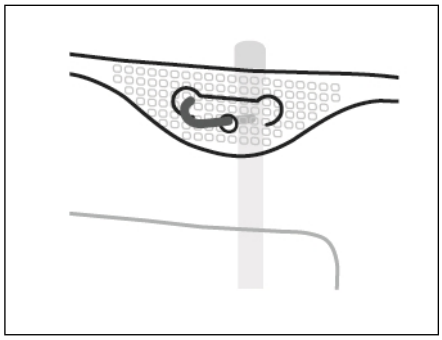
- Shortly before inserting the infusion set, break off the tamper evident arrow flag from the blue infusion port (A).

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.