

Package leaflet: Information for the user

Quatriga 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.

Whats is in this leaflet

1. What Quatriga is and what it is used for
2. What you need to know before you use Quatriga
3. How to use Quatriga
4. Possible side effects
5. How to store Quatriga
6. Contents of the pack and other information

1. What Quatriga is and what it is used for

Quatriga 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 (carbohydrates), lipids (fat) and salts (electrolytes) in a plastic bag and can be given to adults and children aged 2 years and above.

A healthcare professional will give you Quatriga when other forms of feeding are not good enough or have not worked.

2. What you need to know before you use Quatriga

Do not use Quatriga

- if you are allergic (hypersensitive) to active substances or any of the other ingredients of this medicine (listed in section 6)
- if you are allergic to fish or egg
- if you are allergic to peanuts or soya you should not use this product. Quatriga contains soya-bean oil
- if you have too much lipids in the blood (hyperlipidemia)
- if you have serious liver disorder
- if you have blood clotting problems (coagulation disorder)
- if 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) which is uncontrolled
- if you have high blood (serum) levels of the salts (electrolytes) included in Quatriga
- 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 have a defect in your blood clotting system (hemophagocytotic syndrome)
- if you are in an unstable condition, such as after serious trauma, uncontrolled diabetes, acute heart attack, stroke, blood clot, metabolic acidosis (a disturbance resulting in too much acid in the blood), serious infection (severe sepsis), coma and if you don't have enough body fluid (hypotonic dehydration)
- in children under 2 years of age

Warnings and precautions

Talk to your doctor before using Quatriga if you have:

kidney problems
diabetes mellitus
pancreatitis (inflammation of the pancreas)
liver problems
hypothyroidism (thyroid problems)
sepsis (serious infection)

If you during the infusion get fever, rash, swelling, difficulty in breathing, chills, sweating, nausea or vomiting, tell the healthcare professional immediately because these symptoms might be caused by an allergic reaction or that you have been given too much of the medicine.

Your doctor may regularly need to check your blood for liver function tests and other values.

Children and adolescents

Quatriga is not meant for newborn babies or children younger than 2 years of age. Quatriga can be given to children from 2 to 16/18 years old.

Other medicines and Quatriga

Tell your doctor if you are taking, have recently taken or might take any other medicines, even without prescription.

Pregnancy and breast-feeding

Data from using Quatriga during pregnancy or breast-feeding is lacking. Quatriga should therefore be given to pregnant or breast-feeding women only if the doctor find it necessary. The use of Quatriga may be considered during pregnancy and breastfeeding, as advised by your doctor.

Driving and using machines

Not relevant as the medicine is given at the hospital.

3. How to use Quatriga

Always use this medicine exactly as your doctor has told you. Check with your doctor if you are not sure. Your doctor will decide on the dose for you individually depending on your body weight and function. Quatriga will be given to you by a healthcare professional.

If you use more Quatriga than you should

It is unlikely that you will receive too much medicine as Quatriga is given to you by a healthcare professional.

4. Possible side effects

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

Common (may affect up to 1 in 10 people): a slightly raised body temperature.

Uncommon (may affect up to 1 in 100 people): high blood (plasma) levels of compounds from the liver, lack of appetite, nausea, vomiting, chills, dizziness and headache.

Rare (may affect up to 1 in 1,000 people): low or high blood pressure, difficulty in breathing, fast heart beat (tachycardia). Hypersensitivity reactions (that can give symptoms like swelling, fever, fall in blood pressure, skin rashes, wheals (raised red areas), flushing, headache). Sensations of hot and cold. Paleness. Light blue coloured lips and skin (because of too less oxygen in the blood). Pain in the neck, back, bones, chest and loins.

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 Quatriga

Keep this medicine out of the sight and reach of children.

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

Do not use this medicine after the expiry date which is stated on the label on the bag and box. The expiry date refers to the last day of that month.

6. Contents of the pack and other information

What Quatriga contains

<i>The active substances are</i>	<i>g per 1000 ml</i>
Alanine	7.1
Arginine	6.1
Glycine	5.6
Histidine	1.5
Isoleucine	2.5
Leucine	3.8
Lysine (as acetate)	3.4
Methionine	2.2
Phenylalanine	2.6
Proline	5.7
Serine	3.3
Taurine	0.5
Threonine	2.2
Tryptophan	1.0
Tyrosine	0.20
Valine	3.1
Calcium chloride (as dihydrate)	0.28
Sodium glycerophosphate (as hydrate)	2.1
Magnesium sulphate (as heptahydrate)	0.61
Potassium chloride	2.3
Sodium acetate (as trihydrate)	1.7
Zinc sulphate (as heptahydrate)	0.0066
Glucose (as monohydrate)	127
Soya-bean oil, refined	11.4
Medium-chain triglycerides	11.4
Olive oil, refined	9.5
Fish oil, rich in omega-3 fatty acids	5.7

The other ingredients are glycerol, purified egg phospholipids, all-*rac*- α -tocopherol, sodium hydroxide (pH-adjustment), sodium oleate, acetic acid (pH-adjustment), hydrochloric acid (pH-adjustment) and water for injections.

What Quatriga looks like and contents of the pack

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

Pack sizes:

1 x 986 ml, 4 x 986 ml

1 x 1477 ml, 4 x 1477 ml

1 x 1970 ml, 2 x 1970 ml

1 x 2463 ml, 2 x 2463 ml

Marketing Authorisation Holder and Manufacturer

Manufacturer:

Fresenius Kabi AB, SE-751 74 Uppsala, Sweden

Marketing authorisation holder:

[To be completed nationally]

This leaflet was last revised in 2016-03-18

[To be completed nationally]

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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 and manipulations.

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.

Quatriga 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 Quatriga) should be added to Quatriga according to the patients need.

Posology

Adults

Dosage:

The dosage range of 13-31 ml Quatriga/kg bw/day will provide 0.6-1.6 g amino acids/kg bw/day (corresponds to 0.10-0.25 g nitrogen/kg bw/day) and 14-35 kcal/kg bw/day of total energy (12-27 kcal/kg bw/day of non-protein energy).

Infusion rate:

The maximum infusion rate for glucose is 0.25 g/kg bw/h, for amino acids 0.1 g/kg bw/h, and for lipids 0.15 g/kg bw/h.

The infusion rate should not exceed 2.0 ml/kg bw/h (corresponding to 0.25 g glucose, 0.10 g amino acids, and 0.08 g lipids/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 35 ml/kg bw/day.

Paediatric population

Children (2-11 years)

Dosage:

The dose up to 35 ml/kg bw/day should be regularly adjusted to the requirements of the paediatric patient that varies more than in adult patients.

Infusion rate:

The recommended maximum infusion rate is 2.4 ml/kg bw/h (corresponding to 0.12 g amino acids/kg/h, 0.30 g glucose/kg/h and 0.09 g lipids/kg/h). At the recommended maximum infusion rate, do not use an infusion period longer than 14 hours 30 minutes, except in exceptional cases and with careful monitoring. The recommended infusion period is 12-24 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 35 ml/kg bw/day.

Adolescents (12-16/18 years)

In adolescents, Quatriga can be used as in adults.

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 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.

For single use only. Any unused solution remaining after infusion should be discarded.

Compatibility

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

Additions should be made aseptically.

Shelf-life after mixing

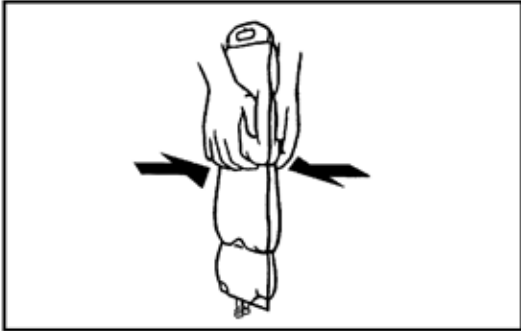
Chemical and physical in-use stability of the mixed three chamber bag has been demonstrated for 36 hours at 25°C. From a microbiological point of view the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and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

Shelf-life after mixing with additives

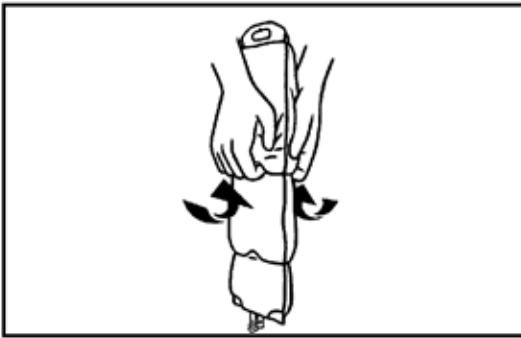
From a microbiological point of view, the product should be used immediately when additions have been made. If not used immediately, the in-use storage time and conditions prior to use are the responsibility of the user. The storage time should normally not be longer than 24 hours at 2-8°C.

Instructions for use *Quatriga*

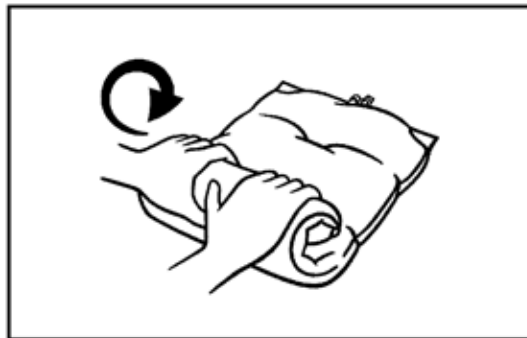
1. To remove the cover wrap hold the bag upright and tear from the notch along the upper edge, then simply tear open the long side, pull off the plastic covering and discard it along with the oxygen absorber.
2. To mix the contents of the bag, place your fingertips on the upper compartment just on the seal as shown on the picture.



3. Grip the sides of the upper chamber with your fingertips and your thumbs and gently roll your knuckles together until the seal breaks.



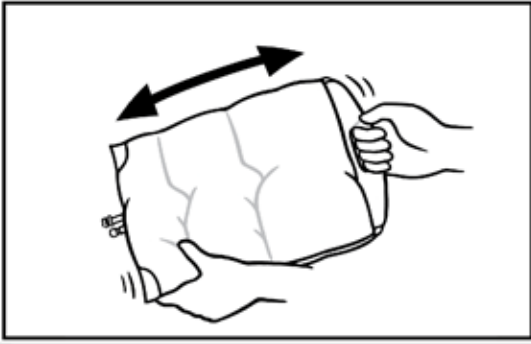
Alternative technique (3): Put the bag, on a flat surface. Roll up the bag by using the handle until the seals are opened. Mix thoroughly by inverting the bag.



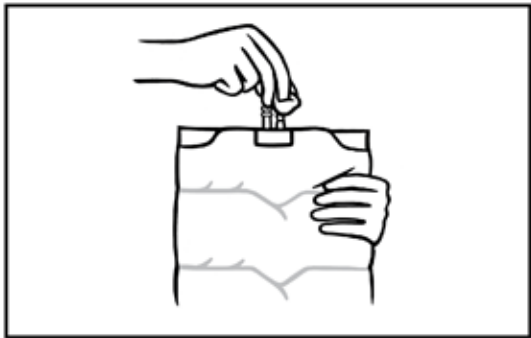
4. The remaining section of seal may now be gently teased apart.



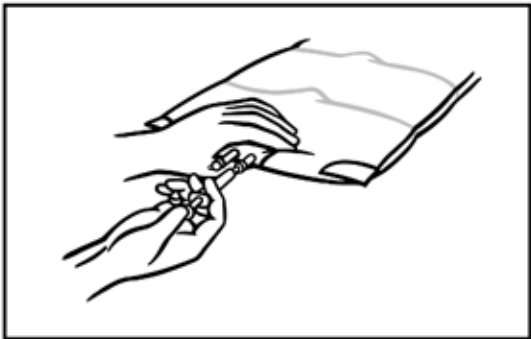
5. To peel open the lower seal, use the same technique as described above. Mix thoroughly by gently inverting the bag end-over-end several times.



6. Before injecting additives swab the additive port with disinfectant.



7. Support the base of the additive port. Fully insert the needle and inject the additives with known compatibility through the centre of the injection site. Mix thoroughly between each addition by inverting the bag several times.



8. Use a non-vented infusion set or close the air-inlet on a vented set. Remove the set port cover by pulling the ring upwards. Support the base of the infusion port. Insert the spike straight into the infusion port. Twist and push the spike through the diaphragm. The spike should be fully inserted to secure it in place.

