Package leaflet: Information for the user

Numeta G19%E 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 child's doctor, pharmacist or nurse.
- If your child gets any side effects, talk to your child's doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Numeta G19%E is and what it is used for

Numeta G19%E is a specialised nutrition emulsion designed for children older than 2 years and adolescents up to 18 years. It is given through a tube which is placed in your child's vein, when your child is not able to eat all of his or her nutrition by mouth.

Numeta is presented in the form of a three chamber bag in which the separate chambers contain:
a 50 % glucose solution
a 5.9% paediatric amino acid solution, with electrolytes
a 12.5% lipid (fat) emulsion

Depending on your child's needs, two or three of these solutions are mixed together in the bag before it is given to your child.

Numeta G19%E must only be used under medical supervision.

2. What you need to know before your child is given Numeta G19%E

Your child should not be given Numeta G19%E, in the following cases:

With 2 solutions mixed together in the bag ("2 in 1"):
- If your child is allergic to egg proteins, soya, peanuts or to any ingredient in the glucose or amino acids chamber (listed in section 6).
- If your child's body has problems using building blocks of protein.
- If your child has high concentrations of any of the electrolytes included in Numeta G19%E in their blood.

- If your child has hyperglycaemia (especially high levels of sugar in his/her blood).

With 3 solutions mixed together in the bag ("3 in 1").
- All of the above situations mentioned for the "2 in 1" plus the following:
- If your child has especially high level of fats in his/her blood.

In all cases, your doctor will base their decision on whether your child should receive this medicine on factors such as age, weight and clinical condition. Your doctor will also consider the results of any tests performed.

Warnings and precautions

Talk to your child's doctor or nurse before they are given Numeta G19%E.

Allergic Reactions:
The infusion must be stopped immediately if any signs or symptoms of an allergic reaction (such as fever, sweating, shivering, headache, skin rashes, or difficulty breathing) develop. This medicinal product contains soybean oil, which may rarely cause hypersensitivity reactions. Uncommonly, it has been observed that some people who are allergic to peanut proteins are also allergic to soybean proteins.

Numeta G19%E contains glucose produced from cornstarch. Therefore, Numeta G19%E should be used with caution in patients with known allergy to corn or corn products.

Risk of particle formation with ceftriaxone (antibiotic):
A certain antibiotic named ceftriaxone must not be mixed or given simultaneously with any calcium containing solutions (including Numeta G19%E) given to you by a drip into your vein. Your doctor knows this and will not give you them together even via different infusion lines or different infusion sites.
However, your doctor may give calcium and ceftriaxone sequentially one after another if infusion lines at different sites are used or if the infusion lines are replaced or were thoroughly flushed with physiological salt solution between the infusions to avoid precipitation.

Formation of small particles in blood vessels of the lungs:
Difficulty breathing could also be a sign that small particles have formed, blocking blood vessels in the lungs (pulmonary vascular precipitates). If your child experiences any difficulty breathing, tell your child's doctor or nurse. They will decide of a course of action to be taken.

Infection and Sepsis:
Your doctor will carefully watch your child for any signs of infection. An "aseptic technique" (germ free technique) when placing and maintaining the catheter as well as when making the nutritional formula can reduce the risk of infection.

Occasionally, children can develop infection and sepsis (bacteria in the blood) when they have a tube in their vein (intravenous catheter). Certain medications and illnesses can increase the risk of developing infection or sepsis. Patients who require parenteral nutrition (giving nutrition through a tube in your child's vein) can be more likely to develop infection from their medical conditions.

Fat overload syndrome:
Fat overload syndrome has been reported with similar products. A reduced or limited ability of the body to remove the fats contained in Numeta G19%E, or an overdose, may result in a "fat overload syndrome" (see section 3 and section 4).

Changes in blood chemistry levels:
Your doctor will check and monitor your child's fluids, blood chemistries and other blood levels since occasionally, refeeding someone who is severely undernourished can result in changes in blood chemistry levels. Extra fluid in the tissues and swelling can also develop. It is recommended that parenteral nutrition is started slowly and carefully.

Monitoring and Adjustment:
Your doctor will be closely monitoring and adjusting Numeta G19%E to meet your child's individual needs if they have the following conditions:

- severe post-traumatic conditions
- severe diabetes mellitus
- shock
- heart attack
- severe infection
- certain types of coma

Use with caution:
Numeta should be used with caution if your child has:

- pulmonary oedema (fluid in the lungs) or heart failure.
- severe liver problems.
- problems in using nutrients.
- high blood sugar.
- kidney problems.
- severe metabolic disorders (when the body cannot break down substances in a normal way).
- blood clotting disorders.

Your child´s fluid status, liver test values and/or blood values will be closely monitored.

Other medicines and Numeta G19%E

Tell your doctor if your child is taking or using, has recently taken or used or might take or use any other medicines.

Numeta G19%E must not be given at the same time as:

- **ceftriaxone** (an antibiotic) not even in separate infusion lines because of the risk of particle formation.
- **blood** through the same infusion tubing due to the risk of pseudoagglutination (red blood cells becoming stuck together in a stack).
- **Ampicillin, fosphenytoin or furosemide** through the same infusion line because of the risk of particle formation

Coumarin and warfarin (Anticoagulants):
Your doctor will carefully watch your child if they are taking coumarin or warfarin. Olive and soybean oil have a natural content of vitamin K1. Vitamin K1 may interfere with drugs such as coumarin and warfarin. These drugs are anticoagulants used to prevent clotting of the blood.

Laboratory tests:
The lipids contained in this emulsion may interfere with the results of certain laboratory tests. Laboratory tests may be performed after a period of 5 to 6 hours when no additional lipids are administered.

Interactions of Numeta G19%E on drugs that may affect potassium levels/metabolism:
Numeta G19%E contains potassium. High levels of blood potassium may cause abnormal heart rhythm. Special care should be taken in patients taking diuretics (drugs to reduce fluid retention) or ACE inhibitors (drugs for high blood pressure) or angiotensin II receptor antagonists (drugs for high blood pressure) or immunosuppressants (drugs that may lower the body's normal immune defences). These types of drugs may increase potassium levels.

Pregnancy, breast-feeding and fertility
There are no adequate data from the use of Numeta in pregnant or breast feeding women. Your doctor will carefully consider the potential risks and benefits for each patient before prescribing Numeta.

3. How Numeta G19%E is given

Your child should always be given Numeta G19%E exactly as the doctor has indicated. Check with your doctor if you are not sure.

Age groups
Numeta G19%E has been designed to meet the nutritional needs of children older than 2 years and adolescents up to 18 years.

Your doctor will decide if this medicine is suitable for your child.

Administration
This medicine is an emulsion for infusion. It is given through a plastic tube in a vein in your child's arm or in a large vein in your child's chest.

Your child's doctor may choose not to give lipids to your child. The design of the Numeta G19%E bag allows only the peel seal between the amino acids/electrolyte and glucose chambers to be broken if necessary. The peel seal between the amino acids and lipid chambers remains intact in this case. The content of the bag can then be infused without lipids.

Dosage and duration of treatment
Your child's doctor will decide the dose and for how long it will be given. The dosage depends on the nutrition needs of your child. The dosage will be based on your child's weight, medical condition, and on their body's ability to break down and use the ingredients in Numeta G19%E. Additional nutrition or proteins given orally/enterally may also be given.

If your child is given too much Numeta G19%E

Symptoms
Too much of this medicine, or giving it too quickly may result in the following:

- nausea (feeling sick)
- vomiting
- shivering
- electrolyte disturbances (improper amounts of electrolytes in the blood)
- signs of hypervolemia (increase of circulating blood volume)
- acidosis (increased acidity of the blood)

In such situations, the infusion must be stopped immediately. Your child's doctor will decide if additional actions are required.

An overdose of fats contained in Numeta G19%E may result in a "fat overload syndrome", which is usually reversible after the infusion is stopped. In newborn babies (neonates) and young children (infants), the fat overload syndrome has been associated with breathing disorder leading to reduced oxygen in the body (respiratory distress) and conditions leading to an increased acidity of the blood (acidosis).

To prevent these events occurring, the doctor will regularly monitor your child's condition and test their blood levels during treatment.

4. Possible side effects

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

If you notice any changes in the way your child feels during or after the treatment, tell your doctor or nurse straight away.

The tests your doctor will perform while your child is taking the medicine should minimise the risk of side effects.

If signs of an allergic reaction occur, the infusion shall be stopped and a doctor contacted immediately. This can be serious and the signs may include:

- sweating
- shivering
- headache
- skin rashes
- breathing difficulties

Other side effects that have been noticed are:

Common: may affect up to 1 in 10 people

- Low phosphate level in the blood (hypophosphataemia)
- High sugar level in the blood (hyperglycaemia)
- High calcium level in the blood (hypercalcaemia)
- High triglycerides level in the blood (hypertriglyceridaemia)

- Electrolyte disturbance (hyponatraemia)

Uncommon: may affect up to 1 in 100 people
- High lipid level in the blood (hyperlipidaemia)
- Condition where bile cannot flow from the liver to the duodenum (cholestasis). The duodenum is a part of the intestines.

*Not known: frequency cannot be estimated from the available data (*These adverse reactions have been reported only for Numeta G13%E Preterm and G16%E when peripherally administered with insufficient dilution).
- Skin necrosis
- Soft tissue injury
- Extravasation

The following side effects have been reported with other products for parenteral nutrition:

The reduced or limited ability to remove the lipids contained in Numeta may result in a "fat overload syndrome". The following signs and symptoms of this syndrome are usually reversible when the infusion of the lipid emulsion is stopped:
- Sudden and abrupt worsening of the patient's medical condition
- High levels of fats in the blood (hyperlipidaemia)
- Fever
- Liver fatty infiltration (hepatomegaly)
- Worsening liver function
- Reduction in red blood cells which can make the skin pale and cause weakness or breathlessness (anaemia)
- Low white blood cell count, which can increase the risk of infection (leukopenia)
- Low platelet count which can increase the risk of bruising and/or bleeding (thrombocytopenia)
- Coagulation disorders which effect the ability of the blood to clot
- Breathing disorder leading to reduced oxygen in the body (respiratory distress)
- Conditions leading to an increased acidity of the blood (acidosis)
- Coma, requiring hospitalisation.

Formation of small particles which may lead to blockage of blood vessels in the lungs (pulmonary vascular precipitates) or difficulty breathing.

Reporting of side effects
If your child gets any side effects talk to your child's doctor 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.

United Kingdom
Via the Yellow Card Scheme: website: www.mhra.gov.uk/yellowcard

Ireland
HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

5. How to store Numeta G19%E

Keep this medicine out of the sight and reach of children when not being administered.

Do not use this medicine after the expiry date which is stated on the bag and the outer packaging (MM/YYYY). The expiry date refers to the last day of that month.

Do not freeze.
Store in the overpouch.

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. Contents of the pack and other information

What Numeta G19%E looks like and contents of the pack

Numeta G19%E is presented in the form of a triple-chamber bag. Each bag contains a sterile combination of a glucose solution, an amino acid solution for children, with electrolytes, and a lipid emulsion, as described below.

Container size	50% glucose solution	5.9% amino acids solution with electrolytes	12.5% lipid emulsion
1000 mL	383 mL	392 mL	225 mL

Appearance before reconstitution:

- The solutions in the amino acids and glucose chambers are clear, colorless or slightly yellow
- The lipid emulsion chamber is a uniform and milky-white liquid

Appearance after reconstitution:

- “2 in 1” solution for infusion is clear, colorless or slightly yellow
- “3 in 1” emulsion for infusion is uniform and milky-white

The three-compartment bag is a multi-layer plastic bag.

To prevent air contact, Numeta is packaged in an oxygen barrier overpouch that contains an oxygen absorber and an oxygen indicator.

Pack sizes

1000 mL bag: 6 units per cardboard box

1 bag of 1000 mL

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

United Kingdom
Baxter Healthcare Ltd
Caxton Way, Thetford,
Norfolk, IP24 3SE
United Kingdom

Ireland
Baxter Holding B.V.
Kobaltweg 49,
3542CE Utrecht,
Netherlands

Manufacturer

BAXTER S.A.
BOULEVARD RENE BRANQUART, 80
7860 LESSINES
BELGIUM

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

Austria Germany	**Numeta G 19 % E Emulsion zur Infusion**
Belgium Luxembourg	**NUMETZAH G19%E, émulsion pour perfusion**
France	**NUMETAH G19 %E émulsion pour perfusion**
Denmark Norway Sweden	**Numeta G19E**
Czech Republic Greece	**NUMETA G 19 % E**
Netherlands	**NUMETA G19%E emulsie voor infusie**
Ireland United Kingdom	**Numeta G19%E, Emulsion for Infusion**
Italy	**NUMETA G19%E emulsione per infusione**
Finland	**Numeta G19E infuusioneste, emulsio**
Poland	**NUMETA G 19 % E**
Portugal	**Numeta G19%E**
Spain	**NUMETA G19%E, emulsión para perfusión**

This leaflet was last revised on 07/2024

The following information is intended for medical or healthcare professionals only*

*Please observe that in certain cases this product may be administered at home by parents or other caregivers. In such cases parents/caregivers should read the following information.

No additions to the bag should be made without first checking the compatibility. Formation of particles or breaking down of the lipid emulsion could result. This can lead to blockage of the blood vessels.

Numeta G19%E should be at room temperature before use.

Before taking Numeta G19%E, the bag will be prepared as shown below.

Confirm that the bag is not damaged. Use the bag only if it is not damaged. An undamaged bag looks like this:

- The non-permanent seals are intact. This is indicated by no mixture of any of the three chambers
- The amino acids solution and the glucose solution are clear, colorless, or slightly yellow without visible particles
- The lipid emulsion is a uniform liquid with a milky white appearance.

Before opening the overpouch, check the colour of the oxygen indicator.

- Compare it to the reference colour printed next to the OK symbol and shown in the printed area of the indicator label.
- Do not use the product if the colour of the oxygen indicator does not correspond to the reference color printed next to the OK symbol.

Figures 1 and 2 illustrate how to remove the protective overpouch. Discard the overpouch, oxygen indicator and oxygen absorber.

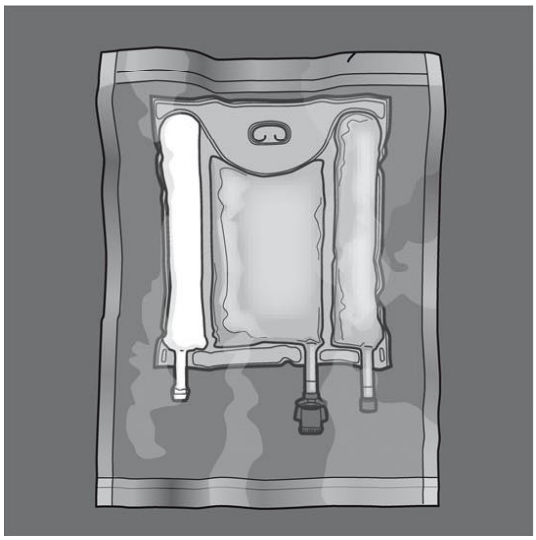


Figure 1

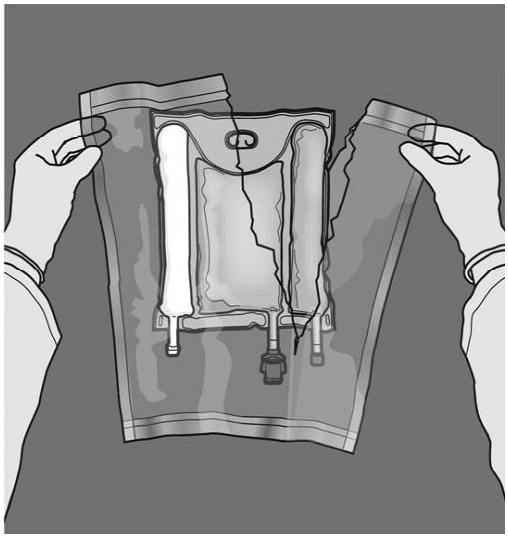


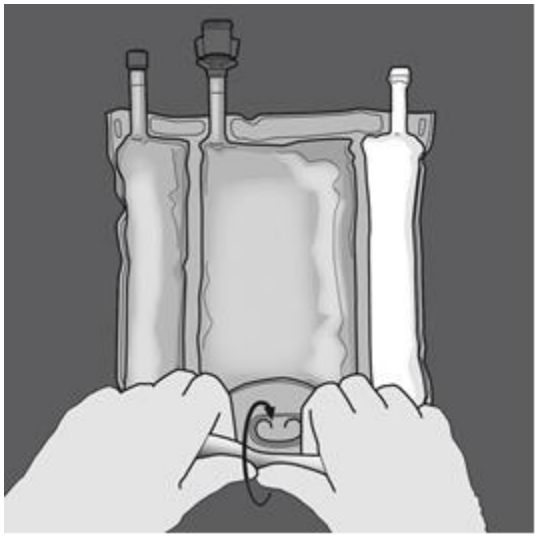
Figure 2

<u>Preparation of the mixed emulsion:</u>

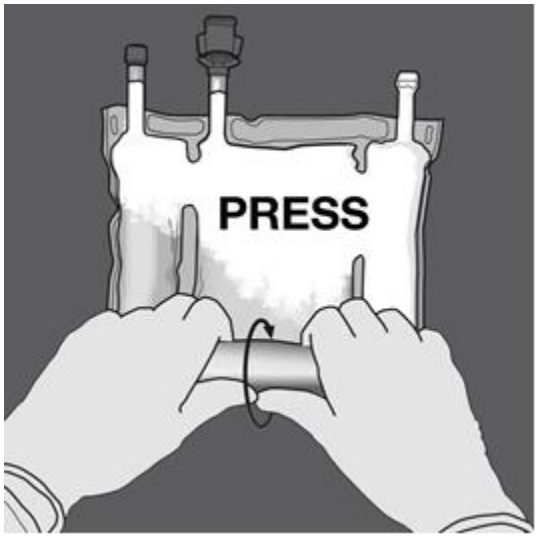
- Ensure that the product is at room temperature when breaking the non-permanent seals.
- Place bag onto a flat clean surface.

Activating the 3 chamber bag (mixing of 3 solutions by breaking two non-permanent seals)

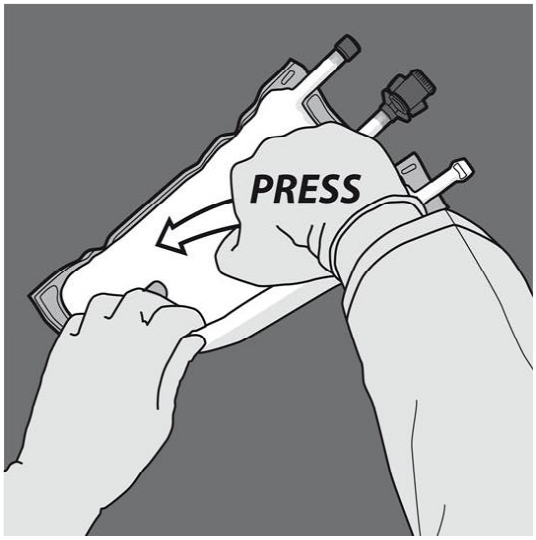
Step 1: Start rolling the bag from the D-hanger side.



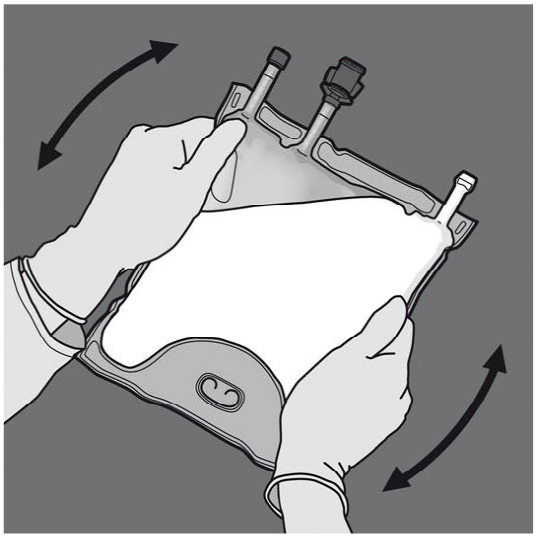
Step 2: Apply pressure until peal seals open.



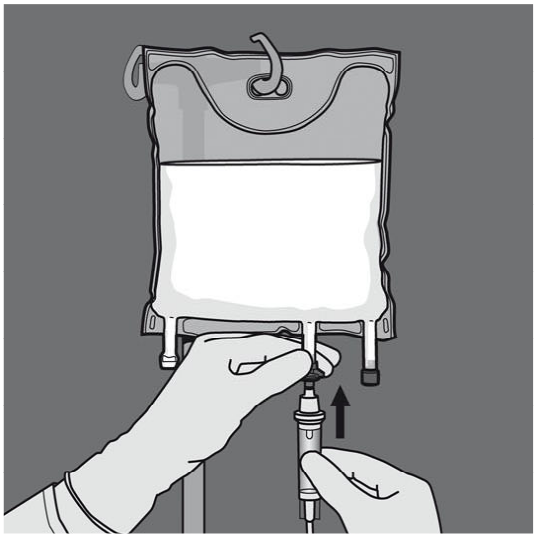
Step 3: Change direction by rolling the bag towards the D-hanger.
Continue until the seal is completely opened.
Proceed the same way to complete the opening of the second peel seal.



Step 4: Turn the bag over at least three times to mix the contents thoroughly.
The appearance of the mixed solution should be a milky-white emulsion.

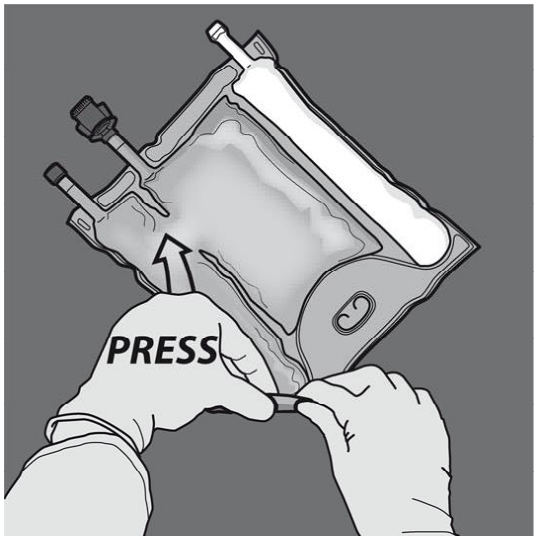


Step 5: Remove the protective cap from the administration site and insert the IV administration set.

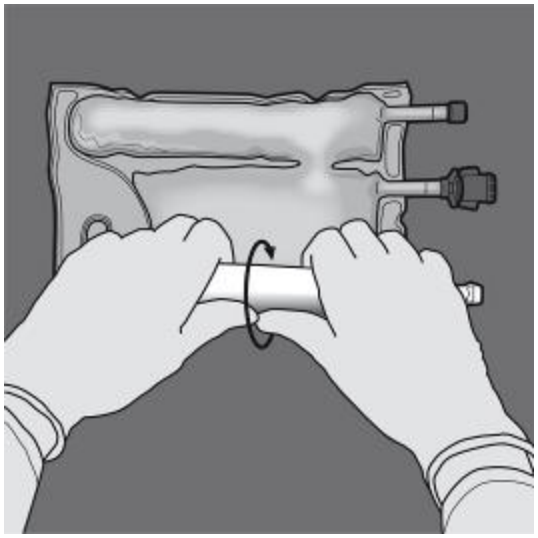


Activating the 2 chambers (mixing 2 solutions by breaking the non-permanent seal between the amino acid and glucose chambers)

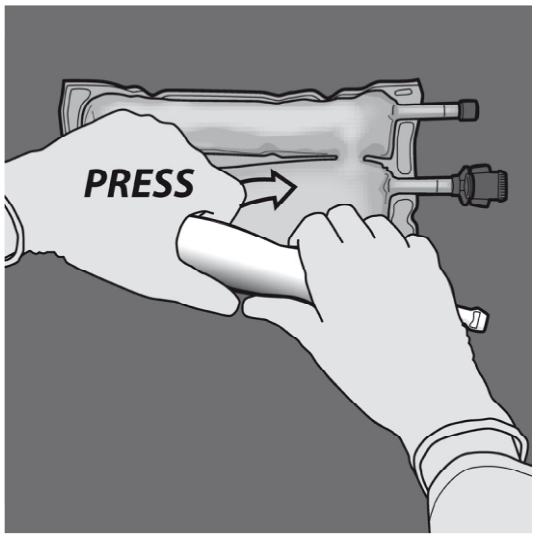
Step 1: To mix only 2 solutions, roll the bag from the top (hanger end) corner of the seal separating the solutions.
Apply pressure to open the seal separating the glucose and amino acids compartments.



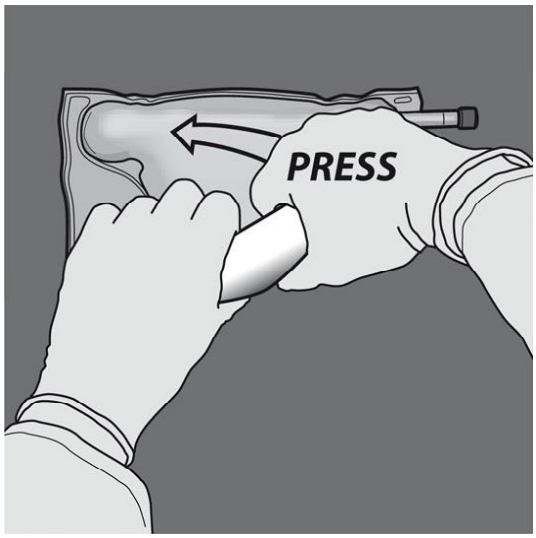
Step 2: Place the bag such that the lipid emulsion compartment is nearest to the operator.
Roll the bag while protecting the lipid emulsion compartment in the palms of the hands.



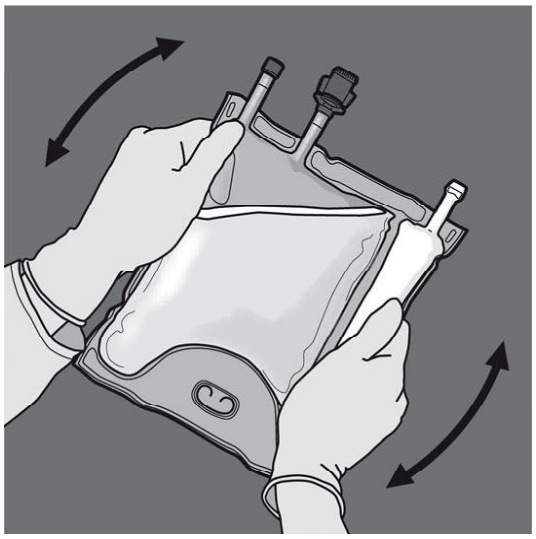
Step 3: Apply pressure with one hand and roll the bag toward the tubes.



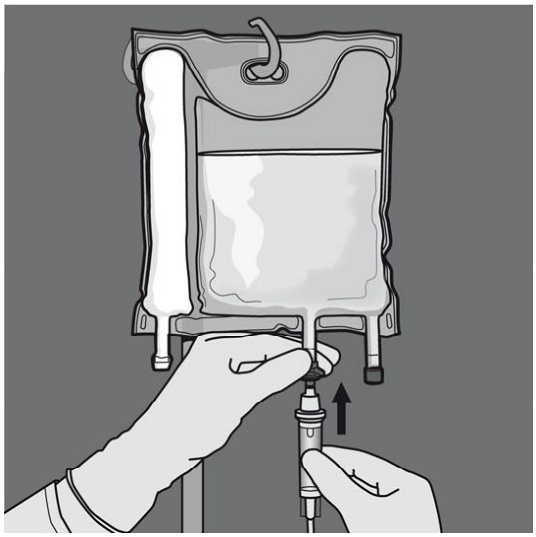
Step 4: Change direction by rolling the bag towards the top (hanger end).
Press with the other hand, continuing until the seal separating the amino acid and glucose solutions is completely opened.



Step 5: Turn the bag over at least three times to mix the content thoroughly.
The appearance of the mixed solution should be clear, colorless or slightly yellow.



Step 6: Remove the protective cap from the administration site and insert the IV administration set.



The flow rate should be increased gradually during the first hour. The administration flow rate must be adjusted based on the following factors:

the dose being administered
the daily volume intake
the duration of the infusion.

Method of administration:

The solution (in bags and administration sets) should be protected from light exposure from point of admixture through administration.

Use of a 1.2 micron filter is recommended for administration of Numeta G19%E.

Due to its high osmolarity, undiluted Numeta G19%E can only be administered through a central vein. However, sufficient dilution of Numeta G19%E with water for injection lowers the osmolarity and allows peripheral infusion.

The formula below indicates how dilution impacts osmolarity of the bags:

$$Final\ osmolarity = \frac{Volume\ of\ bag * Initial\ osmolarity}{Water\ added + Volume\ of\ bag}$$

The table below shows examples of osmolarity for activated 3CB admixture after addition of water for injection:

	Amino Acids, Glucose, and Lipids (Activated 3CB)
Initial volume in the bag (mL)	1000
Initial osmolarity (mOsm/L approximately)	1460
Volume of water added (mL)	1000
Final volume after addition (mL)	2000
Osmolarity after addition (mOsm/L approximately)	730

Addition of additives

Admixtures including trace elements and vitamins should be protected from light, from the point of admixture through administration. Exposure to ambient light generates peroxides and other degradation products that can be reduced by photoprotection

Compatible additives may be added via the injection site into the reconstituted mixture (after the non-permanent seals have been opened and after the contents of the two or three chambers have been mixed).

Vitamins may also be added into the glucose chamber before the mixture is reconstituted (before opening the non-permanent seals and before mixing the solutions and the emulsion).

Possible additions of commercially available trace element solutions (identified as TE1, TE2 and TE4), vitamins (identified as lyophilizate V1 and emulsion V2), and electrolytes in defined quantities are shown in Tables 1-6.

1. *Compatibility with TE4, V1 and V2*

Table 1: Compatibility of 3-in-1 (Activated 3CB) with and without dilution with water

Per 1000 mL (3 in 1 admixture with lipids)						
	Admixture without dilution			Admixture with dilution		
Additives	Included level	Maximum further addition	Maximum total level	Included level	Maximum further addition	Maximum total level
Sodium (mmol)	45.8	105	151	45.8	105	151
Potassium (mmol)	32.0	118	150	32.0	118	150
Magnesium (mmol)	2.6	7.8	10.4	2.6	7.8	10.4
Calcium (mmol)	3.8	20.5	24.3	3.8	20.5	24.3
Phosphate* (mmol)	9.4	14.6	24.0	9.4	14.6	24.0
Trace elements & vitamins	-	34 mL TE4 + 3.4 vials V1 + 38 mL V2	34 mL TE4 + 3.4 vials V1 + 38 mL V2	-	34 mL TE4 + 3.4 vials V1 + 38 mL V2	34 mL TE4 + 3.4 vials V1 + 38 mLV2
Water for Injection	-	-	-	-	1450 mL	1450 mL

* Organic phosphate

Table 2: Compatibility of 2-in-1 (Activated 2CB)

Per 775 mL (2 in 1 admixture without lipids)			
Additives	Included level	Maximum further addition	Maximum total level
Sodium (mmol)	45.1	32.0	77.1
Potassium (mmol)	32.0	45.6	77.6
Magnesium (mmol)	2.6	5.2	7.8
Calcium (mmol)	3.8	19.4	23.2
Phosphate* (mmol)	7.2	16.0	23.2
Trace elements & vitamins	-	10mL TE4 + 1 vial V1	10mL TE4 + 1 vial V1

* Organic phosphate

2. *Compatibility with TE1, V1 and V2*

Table 3: Compatibility of 3-in-1 (Activated 3CB)

Per 1000 mL (3 in 1 admixture with lipids)			
Additives	Included level	Maximum further addition	Maximum total level
Sodium (mmol)	45.8	0	45.8
Potassium (mmol)	32.0	0	32.0
Magnesium (mmol)	2.6	0	2.6
Calcium (mmol)	3.8	6.4	10.2
Phosphate* (mmol)	9.4	0	9.4
Trace elements & vitamins	-	15 mL TE1 + 1 vial V1 + 10 mL V2	15 mL TE1 + 1 vial V1 + 10 mL V2

* Organic phosphate

Table 4: Compatibility of 2-in-1 (Activated 2CB)

Per 775 mL (2 in 1 admixture without lipids)			
Additives	Included level	Maximum further addition	Maximum total level
Sodium (mmol)	45.1	32.0	77.1
Potassium (mmol)	32.0	45.6	77.6
Magnesium (mmol)	2.6	5.2	7.8
Calcium (mmol)	3.8	19.4	23.2
Phosphate* (mmol)	7.2	16.0	23.2
Trace elements & vitamins	-	10mL TE1 + 1 vial V1	10mL TE1 + 1 vial V1

* Organic phosphate

3. Compatibility with TE2, V1 and V2

Table 5: Compatibility of 2-in-1 (Activated 2CB)

Per 775 mL (2 in 1 admixture without lipids)			
Additives	Included level	Maximum further addition	Maximum total level
Sodium (mmol)	45.1	32.0	77.1
Potassium (mmol)	32.0	45.6	77.6
Magnesium (mmol)	2.6	5.2	7.8
Calcium (mmol)	3.8	19.4	23.2
Phosphate* (mmol)	7.2	16.0	23.2
Trace elements & vitamins	-	15mL TE2 + 1 vial V1	15mL TE2 + 1 vial V1

* Organic phosphate

Table 6: Compatibility of 3-in-1 (Activated 3CB)

Per 1000 mL (3 in 1 admixture with lipids)			
Additives	Included level	Maximum further addition	Maximum total level
Sodium (mmol)	45.8	0	45.8
Potassium (mmol)	32.0	0	32.0
Magnesium (mmol)	2.6	0	2.6
Calcium (mmol)	3.8	6.4	10.2
Phosphate* (mmol)	9.4	0	9.4
Trace elements & vitamins	-	15mL TE2 + 1 vial V1 + 10 mL V2	15mL TE2 + 1 vial V1 + 10 mL V2

* Organic phosphate

The composition of vitamins and trace elements preparations are illustrated in Tables 7 and 8.

Table 7: Composition of the commercial trace elements preparation used

Composition per 10mL	**TE1**	**TE2**		**TE4**
Iron	-	8.9µmol or 0.5mg		-
Zinc	38.2µmol or 2.5mg	15.3µmol or 1mg		15.3µmol or 1mg
Selenium	0.253µmol or 0.02mg	0.6µmol or 0.05mg		0.253µmol or 0.02mg
Copper	3.15µmol or 0.2mg	4.7µmol or 0.3mg		3.15µmol or 0.2mg
Iodine	0.0788µmol or 0.01mg	0.4µmol or 0.05mg		0.079µmol or 0.01mg
Fluorine	30µmol or 0.57mg	26.3µmol or 0.5mg		-
Molybdenum	-	0.5µmol or 0.05mg		-
Manganese	0.182µmol or 0.01mg	1.8µmol or 0.1mg		0.091µmol or 0.005mg
Chromium	-	0.4µmol or 0.02mg		-
Cobalt	-	2.5µmol or 0.15mg		-

Table 8:Composition of the commercial vitamin preparations used:

Composition per vial	**V1**	**V2**	
Vitamin B1	2.5mg	-	
Vitamin B2	3.6mg	-	
Nicotinamide	40mg	-	
Vitamin B6	4.0mg	-	
Pantothenic acid	15.0mg	-	
Biotin	60µg	-	
Folic acid	400µg	-	
Vitamin B12	5.0µg	-	
Vitamin C	100mg	-	
Vitamin A	-	2300IU	
Vitamin D	-	400IU	
Vitamin E	-	7IU	
Vitamin K	-	200µg	

To perform an addition:

- Aseptic conditions must be observed
- Prepare the injection site of the bag
- Puncture the injection site and inject the additives using an injection needle or a reconstitution device
- Mix content of the bag and the additives

Preparation of the infusion:

- Aseptic conditions must be observed
- Suspend the bag
- Remove the plastic protector from the administration outlet
- Firmly insert the infusion set spike into the administration outlet

Administration of the infusion:

- For single use only.
- Only administer the product after the non-permanent seals between the two or three chambers have been opened and the contents of the two or three chambers have been mixed.
- Ensure that the final activated 3CB emulsion for infusion does not show any evidence of phase separation or the final 2CB solution for infusion does not show any evidence of particles.
- Immediate use once non-permanent seals are broken is recommended. Numeta G19%E should not be stored for subsequent infusion.Do not connect any partially used bag.

  Do not connect in series in order to avoid the possibility of air embolism due to possible residual gas contained in the primary bag.
- Use of a 1.2 micron filter is recommended for administration of Numeta G19%E.

- Any unused product or waste material and all necessary disposable devices must be properly discarded.

Shelf Life after the Solutions are Mixed

Use the product immediately after the non-permanent seals between the two or three chambers have been opened. Stability studies of the mixtures have been performed for 7 days between 2°C and 8°C followed by 48 hours at 30°C.

Shelf life after supplementation (electrolytes, trace elements, vitamins, water):

For specific admixtures in-use stability of the Numeta formulation has been demonstrated for 7 days between 2°C and 8°C followed by 48 hours at 30°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 to 8°C, unless reconstitution /dilution /supplementation has taken place in controlled and validated aseptic conditions

Do not use Numeta if the bag is damaged. A damaged bag looks like this:

- The non-permanent seals are broken
- Any one of the chambers contains a mixture of any of the solutions
- The amino acids solution and the glucose solution are not clear, colorless, or slightly yellow, and/or contain visible particles
- The lipid emulsion is not a uniform liquid with a milky white appearance.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

What Numeta G19%E contains

The active substances are:

Active Substance	Activated 2CB (775 mL)	Activated 3CB (1000 mL)
Amino Acid Chamber		
Alanine	1.83 g	1.83 g
Arginine	1.92 g	1.92 g
Aspartic acid	1.37 g	1.37 g
Cysteine	0.43 g	0.43 g
Glutamic acid	2.29 g	2.29 g
Glycine	0.91 g	0.91 g
Histidine	0.87 g	0.87 g
Isoleucine	1.53 g	1.53 g
Leucine	2.29 g	2.29 g
Lysine monohydrate (equivalent to Lysine)	2.82 g (2.51 g)	2.82 g (2.51 g)
Methionine	0.55 g	0.55 g
Ornithine hydrochloride (equivalent to Ornithine)	0.73 g (0.57 g)	0.73 g (0.57 g)
Phenylalanine	0.96 g	0.96 g
Proline	0.69 g	0.69 g
Serine	0.91 g	0.91 g
Taurine	0.14 g	0.14 g
Threonine	0.85 g	0.85 g
Tryptophan	0.46 g	0.46 g
Tyrosine	0.18 g	0.18 g
Valine	1.74 g	1.74 g
Sodium chloride	1.79 g	1.79 g
Potassium acetate	3.14 g	3.14 g
Calcium chloride dihydrate	0.56 g	0.56 g
Magnesium acetate tetrahydrate	0.55 g	0.55 g
Sodium glycerophosphate hydrated	2.21 g	2.21 g
Glucose Chamber		
Glucose monohydrate	210.65 g	210.65 g

Active Substance	Activated 2CB (775 mL)	Activated 3CB (1000 mL)
(equivalent to glucose anhydrous)	(191.50 g)	(191.50 g)
Lipid Chamber		
Refined olive oil (approximately 80%) + Refined soya bean oil (approximately 20%)	-	28.1 g

2CB=two chamber bag, 3CB= three chamber bag

The reconstituted solution/emulsion provides the following:

Composition				
	Activated 2CB		**Activated 3CB**	
Per volume unit (mL)	**775**	**100**	**1000**	**100**
Nitrogen (g)	3.5	0.45	3.5	0.35
Amino acids (g)	23.0	3.0	23.0	2.3
Glucose (g)	192	24.7	192	19.2
Lipids (g)	0	0	28.1	2.8
Energy				
Total calories (kcal)	858	111	1139	114
Non-protein calories (kcal)	766	99	1047	105
Glucose calories (kcal)	766	99	766	77
Lipid calories (kcal) [a]	0	0	281	28
Non-prot calories / nitrogen (kcal/g N)	220	220	301	301
Lipid calories / non-protein calories (%)	NA	N/A	27	27
Lipid calories / total calories (%)	NA	N/A	25	25
Electrolytes				
Sodium (mmol)	45.1	5.8	45.8	4.6
Potassium (mmol)	32.0	4.1	32.0	3.2
Magnesium (mmol)	2.6	0.33	2.6	0.26
Calcium (mmol)	3.8	0.50	3.8	0.38
Phosphate (mmol) [b]	7.2	0.93	9.4	0.93
Acetate (mmol)	37.1	4.8	37.1	3.71
Malate (mmol)	8.8	1.1	8.8	0.88
Chloride (mmol)	42.6	5.5	42.6	4.3
pH (approx.)	5.5	5.5	5.5	5.5
Osmolarity approx. (mOsm/L)	1835	1835	1460	1460

a Includes calories from egg phospholipids for injection

b Includes phosphate from egg phospholipids for injection component of the lipid emulsion

The other ingredients are:

L-Malic acid [a]
Hydrochloric acid [a]
Egg phospholipids for injection
Glycerol
Sodium oleate
Sodium hydroxide [a]
Water for injections

a for pH adjustment