PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

NUMETA G13E

Emulsion for Infusion

Alanine, arginine, aspartic acid, cysteine, glutamic acid, glycine, histidine, isoleucine, leucine, lysine monohydrate, methionine, ornithine hydrochloride, phenylalanine, proline, serine, taurine, threonine, tryptophan, tyrosine, valine, potassium acetate, calcium chloride dihydrate, magnesium acetate tetrahydrate, sodium glycerophosphate hydrated, glucose monohydrate, refined olive oil and refined soya-bean oil.

Contains sugar (glucose).

Read all of this leaflet carefully before your child is given NUMETA G13E

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your child's doctor, pharmacist, nurse or other health care provider.
- 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 G13E is and what it is used for
2. What you need to know before your child is given NUMETA G13E
3. How NUMETA G13E is given
4. Possible side effects

5. How to store NUMETA G13E

6. Contents of the pack and other information

1. What NUMETA G13E is and what it is used for

NUMETA G13E is a specialised nutrition emulsion designed for preterm new-borns. 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 G13E 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 G13E must only be used under medical supervision.

2. What you need to know before your child is given NUMETA G13E

Your child should not be given NUMETA G13E:

With the glucose and amino acid/electrolyte solutions mixed together in the bag ("2 in 1")

- If your child is allergic to egg, soya, peanuts, any of the active substances or any of the inactive substances of NUMETA G13E, or any of the components of the container (see section 6).
- If your child's body has problems using building blocks of protein (abnormal amino acid metabolism).

- If your child has high concentrations of any of the electrolytes (sodium, potassium, magnesium, calcium and/or phosphorus) included in NUMETA G13E in their blood.
- NUMETA G13E (or other calcium containing solutions) must not be given at the same time as ceftriaxone (an antibiotic), even if separate infusion lines are used. There is a risk of particle formation in the new-born's bloodstream, which may result in death.
- If your child has hyperglycaemia (especially high levels of sugar in his/her blood).

With the glucose, amino acid/electrolyte and lipid 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 lipids (fats) in his/her blood
- If your child has a lipid metabolism disorder (a disorder whereby fat is not easily broken down) characterised by hypertriglyceridaemia (high blood levels of fats called triglycerides).

In all cases, your child's doctor will base their decision on whether your child should receive NUMETA G13E on factors such as age, weight and clinical condition. Your child's doctor will also consider the results of any tests performed.

Warnings and precautions

Talk to your child's doctor or healthcare professional before they are given NUMETA G13E:

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. NUMETA G13E contains soybean oil, which may rarely cause allergic reactions. Uncommonly, it has been observed that some people who are allergic to peanut proteins are also allergic to soybean proteins.

NUMETA G13E contains glucose produced from cornstarch. Therefore, NUMETA G13E 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 G13E) given to you by a drip into your vein. Your child's doctor knows this and will not give these medicines together, even via different infusion lines or different infusion sites.

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 on a course of action to be taken.

Infection and sepsis:

Your child's doctor will carefully watch your child for any signs of infection. An "aseptic technique" (i.e., 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 G13E, or an overdose, may result in a "fat overload syndrome" (see section 4 – Possible Side Effects).

Changes in blood chemistry levels:

Your child's doctor will check and monitor your child's fluids, blood chemistries and other blood values during treatment with NUMETA G13E. Occasionally refeeding someone who is severely undernourished can result in major changes in blood chemistry levels that may need to be corrected. 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 child's doctor will be closely monitoring and adjusting NUMETA G13E to meet your child's individual needs especially 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 G13E should be used with caution if your child has:

- pulmonary oedema (fluid in the lungs) or heart failure.
- severe liver problems.
- 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 body fluid status, liver test values and/or other blood values will be closely monitored.

There is limited information on giving NUMETA G13E to preterm (premature) infants less than 28-week gestational age.

Other medicines and NUMETA G13E

Always tell your healthcare professional if your child is taking any other medicine (This includes complementary or traditional medicines).

NUMETA G13E 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 child’s doctor will carefully watch your child if they are taking coumarin or warfarin. These medicines are anticoagulants used to prevent clotting of the blood. Olive and soybean oil have a natural content of vitamin K1. Vitamin K1 may interfere with medicines such as coumarin and warfarin.

Laboratory tests:

The lipids (fats) 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 following the use of lipids or when no additional lipids are administered.

Interactions of NUMETA G13E with medicines that may affect potassium levels/metabolism:

NUMETA G13E contains potassium. High levels of blood potassium may cause abnormal heart rhythm. Special care should be taken in patients taking diuretics (medicines to reduce fluid retention) or ACE inhibitors (medicines for high blood pressure) or angiotensin II receptor antagonists (medicines for high blood pressure) or immunosuppressants (medicines that may lower the body's normal immune defences). These types of medicines may increase potassium levels.

Pregnancy, breastfeeding and fertility

Not applicable since NUMETA G13E is intended for pre-term newborn infants.

Driving and using machines

Not applicable since NUMETA G13E is intended for pre-term newborn infants.

Important information about some of the ingredients of NUMETA G13E:

NUMETA G13E contains glucose, which may have an effect on your child's blood sugar levels if your child has diabetes.

NUMETA G13E contains glucose produced from cornstarch. Therefore, NUMETA G13E should be used with caution in patients with known allergy to corn or corn products.

NUMETA G13E contains soybean oil, which may rarely cause allergic reactions. Uncommonly, it has been observed that some people who are allergic to peanut proteins are also allergic to soybean proteins.

3. How NUMETA G13E is given

You will not be expected to give your child NUMETA G13E. It will be given to them by a person qualified to do so.

Age group

NUMETA G13E has been designed to meet the nutritional needs of pre-term new-borns.

NUMETA G13E may not be appropriate for some pre-term infants, as their condition may require individualised formulations to meet their specific nutritional needs. Your child's doctor will decide if this medicine is suitable for your child.

Administration

NUMETA G13E 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 (fats) to your child. The design of the NUMETA G13E 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 G13E.

Additional nutrition or proteins given orally/enterally may also be given.

If your child is given too much NUMETA G13E

Since a healthcare professional will administer NUMETA G13E, he/she will control the dosage.

However, in the event of overdosage, your child's doctor will manage the overdosage.

4. Possible side effects

NUMETA G13E can have side effects.

Not all side effects reported for NUMETA G13E are included in this leaflet. Should your child's general health worsen or if your child experiences any untoward effects while receiving NUMETA G13E, please consult your child's doctor, pharmacist or other healthcare professional for advice.

The tests your child's doctor will perform while your child is taking NUMETA G13E 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:

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

Other side effects that have been noticed are:

Frequent side effects:

- Low phosphate level in the blood (hypophosphataemia) – seen in a blood test
- High sugar level in the blood (hyperglycaemia) – seen in a blood test
- High calcium level in the blood (hypercalcaemia) – seen in a blood test
- High triglycerides (types of fat) level in the blood (hypertriglyceridaemia) – seen in a blood test
- Electrolyte disturbance (hyponatraemia) – seen in a blood test

Less frequent side effects:

- High lipid (fat) level in the blood (hyperlipidaemia) – seen in a blood test
- Condition where bile cannot flow from the liver to the duodenum (cholestasis). The duodenum is a part of the intestines.

Frequency unknown:

- Skin necrosis (death of cells or tissue through disease or injury)
- Soft tissue injury (trauma to any skin, muscle, tendon, or ligament in the body)
- Extravasation (The leakage of fluid from a blood vessel or tube into the tissue around it)

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

- The reduced or limited ability to remove the lipids (fats) contained in NUMETA G13E 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.

If you notice any side effects not mentioned in this leaflet, please inform your child's doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of NUMETA G13E.

5. How to store NUMETA G13E

Store all medicines out of reach of children.

Store at or below 25 °C.

Do not freeze.

Store in over-pouch.

Do not use NUMETA G13E after the expiry date which is stated on the bag and the outer packaging. The expiry date refers to the last day of that month.

Shelf life after reconstitution

It is recommended that NUMETA G13E be used immediately after the non-permanent seals between the two or three chambers have been opened. However, stability data of the reconstituted mixtures supports 7 days between 2 °C and 8 °C followed by a maximum of 48 hours at or below 30 °C.

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

For specific admixtures physical stability of the NUMETA G13E formulation has been demonstrated for 7 days between 2 °C and 8 °C followed by a maximum of 48 hours at or below 30 °C. Information on these additions is specified in section 6.6.

From a microbiological point of view, NUMETA G13E 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 °C to 8 °C, unless reconstitution / dilution / supplementation has taken place in controlled and validated aseptic conditions.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g toilets).

6. Contents of the pack and other information

What NUMETA G13E contains

The active substances in NUMETA G13E are:

Composition		
Active Substance	**Activated 2CB (240 ml)**	**Activated 3CB (300 ml)**
Amino Acid Chamber		
Alanine	0,75 g	0,75 g
Arginine	0,78 g	0,78 g
Aspartic acid	0,56 g	0,56 g
Cysteine	0,18 g	0,18 g
Glutamic acid	0,93 g	0,93 g
Glycine	0,37 g	0,37 g
Histidine	0,35 g	0,35 g
Isoleucine	0,62 g	0,62 g
Leucine	0,93 g	0,93 g
Lysine monohydrate (equivalent to Lysine)	1,15 g (1,03 g)	1,15 g (1,03 g)
Methionine	0,22 g	0,22 g
Ornithine hydrochloride (equivalent to Ornithine)	0,30 g (0,23 g)	0,30 g (0,23 g)
Phenylalanine	0,39 g	0,39 g
Proline	0,28 g	0,28 g
Serine	0,37 g	0,37 g
Taurine	0,06 g	0,06 g
Threonine	0,35 g	0,35 g
Tryptophan	0,19 g	0,19 g

Tyrosine	0,07 g	0,07 g
Valine	0,71 g	0,71 g
Potassium acetate	0,61 g	0,61 g
Calcium chloride dihydrate	0,55 g	0,55 g
Magnesium acetate tetrahydrate	0,10 g	0,10 g
Sodium glycerophosphate hydrated	0,98 g	0,98 g
Glucose Chamber		
Glucose monohydrate (equivalent to glucose anhydrous)	44,00 g (40,00 g)	44,00 g (40,00 g)
Lipid Chamber		
Refined olive oil (approximately 80 %) + Refined soya bean oil (approximately 20 %)	-	7,5 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)	**240**	**100**	**300**	**100**
Nitrogen (g)	1,4	0,59	1,4	0,47
Amino acids (g)	9,4	3,9	9,4	3,1
Glucose (g)	40,0	16,7	40,0	13,3

Lipids (g)	0	0	7,5	2,5
Energy				
Total calories (kcal)	198	82	273	91
Non-protein calories (kcal)	160	67	235	78
Glucose calories (kcal)	160	67	160	53
Lipid calories [a] (kcal)	0	0	75	25
Non-prot calories / nitrogen (kcal/g N)	113	113	165	165
Lipid calories (% non-protein calories)	N/A	N/A	32	32
Lipid calories (% total calories)	N/A	N/A	28	28
Electrolytes				
Sodium (mmol)	6,4	2,7	6,6	2,2
Potassium (mmol)	6,2	2,6	6,2	2,1
Magnesium (mmol)	0,47	0,20	0,47	0,16
Calcium (mmol)	3,8	1,6	3,8	1,3
Phosphate [b] (mmol)	3,2	1,3	3,8	1,3
Acetate (mmol)	7,2	3,0	7,2	2,4
Malate (mmol)	3,2	1,3	3,2	1,1
Chloride (mmol)	9,3	3,9	9,3	3,1
pH (approx.)	5,5	5,5	5,5	5,5
Osmolarity approx. (mOsm/l)	1400	1400	1150	1150

[a] Includes calories from egg phosphatide

[b] Includes phosphate from egg phosphatide component of the lipid emulsion

The other ingredients are: L-Malic acid[a], hydrochloric acid[a], purified egg phosphatide, glycerol, sodium oleate, sodium hydroxide[a], water for injections.

[a] for pH adjustment

What NUMETA G13E looks like and contents of the pack

NUMETA G13E is presented in the form of a three chamber bag. Each bag contains a sterile non-pyrogenic combination of a glucose solution, a paediatric amino acids solution, 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
300 ml	80 ml	160 ml	60 ml

Appearance before reconstitution:

- The solutions in the amino acids and glucose chambers are clear, colourless or slightly yellow, practically free from particles.
- The lipid emulsion is homogeneous and milky-white.

Appearance after reconstitution:

- “2 in 1” solution (amino acids/electrolytes and glucose) for infusion is clear, colourless or slightly yellow
- “3 in 1” emulsion for infusion is uniform and milky-white

The three-chamber full non-PVC bag consists of the following components:

- A multi-layer plastic sheeting.
- A port tube on the compartment containing the lipid emulsion. It is sealed off after filling to prevent additions to this chamber.
- Two port tubes on the amino acid solution and glucose solution chambers:

- An injection site that closes the port tube of the glucose compartment.
- An administration site that closes the port tube of the amino acid compartment.

All components are free of natural latex rubber.

To prevent air contact, the bag is packaged in an oxygen barrier over-pouch that contains an oxygen absorber sachet and an oxygen indicator.

Available pack sizes:

300 ml bags: 10 units per cardboard box

1 bag of 300 ml

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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