NUMETA G19E Dosing Chart - 1460 mosm/l Osmolarity

Activated as a 3-chamber bag

NUMETA G19E
1000 ml
Children older than 2 years & adolescents 16-18 years old

2018 ESPGHAN Guidelines[1]:

Energy (kcal/kg/d)	Acute*	Stable*	Recovery*
2-7 years	40-45	55-60	65-75
7-12 years	30-40	40-55	55-65
12-18 years	20-30	25-40	30-55

Amino Acid (g/kg/d)	
2-3 years	1,0-2,5
3-18 years	1,0-2,0

	ESPGHAN Guidelines[1] Max/Target								
Volume (ml/kg/d)	**120**	**20**	**30**	**40**	**50**	**60**	**70**	**80**	**83**
Amino Acids (g/kg/d)	**2,5**	**0,5**	**0,7**	**0,9**	**1,2**	**1,4**	**1,6**	**1,8**	**1,9**
Glucose (g/kg/d)	8,6	3,8	5,8	7,7	9,6	11,5	13,4	15,4	15,9
Lipids^^ (g/kg/d)	3	0,6	0,8	1,1	1,4	1,7	2,0	2,2	2,3
Total Energy (kcal/kg/d)	**75**	**23**	**34**	**46**	**57**	**68**	**80**	**91**	**95**
Sodium (mmol/kg/d)	3	0,9	1,4	1,8	2,3	2,7	3,2	3,7	3,8
Potassium (mmol/kg/d)	3	0,6	1,0	1,3	1,6	1,9	2,2	2,6	2,7
Magnesium (mmol/kg/d)	0,1	0,05	0,08	0,10	0,13	0,16	0,18	0,21	0,22
Calcium (mmol/kg/d)	0,4	0,1	0,1	0,2	0,2	0,2	0,3	0,3	0,3
Phosphate (mmol/kg/d)	0,7	0,2	0,3	0,4	0,5	0,6	0,7	0,8	0,8
Chloride (mmol/kg/d)	4	0,9	1,3	1,7	2,1	2,6	3,0	3,4	3,5

*Recommendations in the acute and stable phase applies in the critical care setting. Recommendations in the recovery phase can be applied for all other patients.

^^LA=linoleic acid 0,1 g linoleic acid are provided by 20 ml Numeta G19E containing 0,6 g of a lipid emulsion composed of 80% olive oil and 20% soybean oil.

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NUMETA G19E

This abbreviated summary of product characteristics (SPC) is intended for international use. Please note that it may differ from the licensed SPC in the country where you are practicing. Therefore, please always consult your country-specific SPC or package leaflet available at www.produktresume.dk in Denmark; www.fimea.fi in Finland, www. felleskatalogen. no in Norway or www.fass.se in Sweden.

NAME OF THE MEDICINAL PRODUCT

Numeta G19E emulsion for infusion

QUALITATIVE AND QUANTITATIVE COMPOSITION

This medicinal product 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.

Product	Container size	50% glucose solution	5.9% amino acids solution with electrolytes	12.5% lipid emulsion
Numeta G19E	1000 ml	383 ml	392 ml	225 ml

If lipid administration is undesirable, the design of the bag allows the possibility to activate only the peel seal between the amino acids/electrolytes and glucose chambers, leaving the peel seal between the amino acids and lipid chambers intact. The content of the bag can subsequently be infused with or without lipids.

CLINICAL PARTICULARS

Therapeutic indications

Numeta G19E is indicated for parenteral nutrition in children older than 2 years and adolescents 16-18 years old when oral or enteral nutrition is not possible, insufficient or contraindicated.

Posology and method of administration

Posology

The dosage depends on energy expenditure, the patient's weight, age, clinical status, and on the ability to metabolize the constituents of Numeta G19E, as well as on additional energy or proteins given orally/enterally. Total electrolyte and macronutrient composition is dependent on the number of activated chambers.

The maximal recommended hourly rate of infusion and volume per day depend on the constituent. The first of these limits to be reached sets the maximum daily dose. The guidelines for maximal recommended hourly rate of infusion and volume per day are:

For Numeta G19E:

	Activated 2CB (775 ml)	Activated 3CB (1000 ml)
Maximal rate of infusion in ml/kg/h	4,7	4,6
Maximal amount in ml/kg/day	64,8	83,6

Method of administration

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

The flow rate should be increased gradually during the first hour. Upon discontinuation of Numeta G19E, the flow rate should be decreased gradually during the last hour. The administration flow rate must be adjusted taking into account the dose being administered, the daily volume intake, and the duration of the infusion.

The same bag should not be activated, hung and infused longer than 24 hours. Cyclic infusions should be managed according to the patient's metabolic tolerance.

Treatment with parenteral nutrition may be continued for as long as is required by the patient's clinical conditions.

Due to its high osmolarity, undiluted Numeta G19E can only be administered through a central vein. However, sufficient dilution of Numeta G19E with water for injection lowers the osmolarity and allows peripheral infusion.

Contraindications

The general contraindications for administering Numeta G19E as an activated 2 chamber bag for intravenous infusion are as follows:

- Hypersensitivity to egg, soy or peanut proteins, or to any of the active substances, excipients, or components of the container
- Congenital abnormality of the amino acid metabolism
- Pathologically elevated plasma concentrations of sodium, potassium, magnesium, calcium and/or phosphorus
- Severe hyperglycaemia

The addition of lipids (administering Numeta G19E as an activated 3 chamber bag for intravenous emulsion) is contraindicated in the following additional clinical situations:

- Severe hyperlipidaemia, or severe disorders of lipid metabolism characterized by hypertriglyceridemia

Undesirable effects

The pooled data from clinical trials and the post-marketing experience indicate the following adverse drug reactions (ADRs) related to Numeta:

Clinical Trial and Post-marketing Experience Adverse Reactions		
System Organ Class (SOC)	Frequency**	Preferred MedDRA Term
METABOLISM AND NUTRITION DISORDERS	Common	Hypophosphataemia*
	Common	Hyperglycaemia*
	Common	Hypercalcaemia*
	Common	Hypertriglyceridaemia*
	Uncommon	Hyperlipidaemia
	Common	Hyponatraemia*
HEPATOBILIARY DISORDERS	Uncommon	Cholestasis
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	Not known	Skin necrosis***
	Not known	Soft tissue injury***
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITION	Not known	Extravasation***

* Blood samples drawn during the infusion (without fasting conditions).
**Frequency is based upon the following categories: Very Common (≥1/10); Common (≥1/100 - <1/10), Uncommon (≥1/1,000 - <1/100), Rare (≥1/10,000 - <1/1,000), Very Rare (<1/10,000), Not known (cannot be estimated based on available data).
*** These adverse reactions have been reported only for Numeta G13E and G16E when peripherally administered with insufficient dilution.

The following adverse reactions have been reported with other parenteral nutrition admixtures:

Fat overload syndrome: may be caused by inappropriate administration (e.g. overdose and/or infusion rate higher than recommended); however the signs and symptoms of this syndrome may also occur when the product is administered according to instructions. The reduced or limited ability to metabolize the lipids contained in Numeta G19E accompanied by prolonged plasma clearance may result in a "fat overload syndrome". This syndrome is associated with a sudden deterioration in the patient's clinical condition and is characterized by findings such as hyperlipidemia, fever, liver fatty infiltration (hepatomegaly), deteriorating liver function, anemia, leukopenia, thrombocytopenia, coagulation disorders and central nervous system manifestations (e.g. coma). The syndrome is usually reversible when the infusion of the lipid emulsion is stopped.
Pulmonary vascular precipitates (pulmonary vascular embolism and respiratory distress).

Reference:
1. ESPGHAN/ESPEN/ESPR/CSPEN guidelines on pediatric parenteral nutrition. Clinical Nutrition 2018:37.

Precautions

Do not add other medicinal products or substances to one of the three chambers of the bag or to the reconstituted solution/emulsion without first confirming their compatibility and the stability of the resulting preparation.

Numeta G19E should be protected from light from the point of admixture through administration

Cardiovascular: Use with caution in patients with pulmonary edema or heart failure. Fluid status should be closely monitored. Renal: Use with caution in patients with renal insufficiency. Fluid and electrolyte status, including magnesium, should be closely monitored in these patients. Severe water and electrolyte equilibration disorders, severe fluid overload states, and severe metabolic disorders should be corrected before starting the infusion. Hepatic/Gastrointestinal: Use with caution in patients with severe liver insufficiency, including cholestasis, or elevated liver enzymes. Liver function parameters should be closely monitored. Endocrine and Metabolism: Metabolic complications may occur if the nutrient intake is not adapted to the patient's requirements, or the metabolic capacity of any given dietary component is not accurately assessed. Adverse metabolic effects may arise from administration of inadequate or excessive nutrients or from inappropriate composition of an admixture for a particular patient's needs. Hematologic: Use with caution in patients with severe blood coagulation disorders. Blood count and coagulation parameters should be closely monitored.

For the detailed posology, Special warnings and precautions for use, interactions, pharmacological properties and pharmaceutical particulars, please refer to the full SPC.

Medicinal products are subject to medical prescription

Revised May 2019

Country specific information

Denmark: Udlevering: B, Tilskud: Ikke tilskudsberettiget, For prices see: www.medicin priser.dk. Norway: Reseptgruppe: C, Blå resept: Nei, For prices, see: www.legemiddelsok.no. ATC code: B05BA10.

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Baxter A/S
P 4816 6400

NUMETA G19E Dosing Chart - **Diluted** to 846 mosm/l Osmolarity (725 ml WFI added) Activated as a 3-chamber bag

NUMETA G19E
1750 ml
Children older than 2 years & adolescents 16-18 years old

2018 ESPGHAN Guidelines[1]:

Energy (kcal/kg/d)	Acute*	Stable*	Recovery*
2-7 years	40-45	55-60	65-75
7-12 years	30-40	40-55	55-65
12-18 years	20-30	25-40	30-55

Amino Acid (g/kg/d)	
2-3 years	1,0-2,5
3-18 years	1,0-2,0

	ESPGHAN Guidelines[1] Max/Target									
Volume (ml/kg/d)	**120**	**40**	**50**	**60**	**70**	**80**	**90**	**100**	**110**	**120**
Amino Acids (g/kg/d)	**2,5**	**0,5**	**0,7**	**0,8**	**0,9**	**1,1**	**1,2**	**1,3**	**1,5**	**1,6**
Glucose (g/kg/d)	8,6	4,5	5,6	6,7	7,8	8,9	10	11,1	12,2	13,4
Lipids^^ (g/kg/d)	3	0,6	0,8	1,0	1,1	1,3	1,5	1,6	1,8	1,9
Total Energy (kcal/kg/d)	**75**	**26**	**33**	**40**	**46**	**53**	**59**	**66**	**73**	**79**
Sodium (mmol/kg/d)	3	1,1	1,3	1,6	1,9	2,1	2,4	2,7	2,9	3,2
Potassium (mmol/kg/d)	3	0,7	0,9	1,1	1,3	1,5	1,7	1,9	2,0	2,2
Magnesium (mmol/kg/d)	0,1	0,06	0,08	0,09	0,11	0,12	0,14	0,15	0,17	0,18
Calcium (mmol/kg/d)	0,4	0,1	0,1	0,1	0,2	0,2	0,2	0,2	0,2	0,3
Phosphate (mmol/kg/d)	0,7	0,2	0,3	0,3	0,4	0,4	0,5	0,5	0,6	0,6
Chloride (mmol/kg/d)	4	1,0	1,2	1,5	1,7	1,9	2,2	2,4	2,7	2,9

*Recommendations in the acute and stable phase applies in the critical care setting. Recommendations in the recovery phase can be applied for all other patients.

^^LA=linoleic acid 0,1 g linoleic acid are provided by 35 ml Numeta G19E diluted down to 846 mosm/l and containing 0,6 g of a lipid emulsion composed of 80% olive oil and 20% soybean oil.

WFI - Water for Injection

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