

iCAN Neonatology

Tuesday, 15 June 2021, 16:00–18:30 CET (SE, DK, NO) / 17:00–19:30 EET (FI)

Program Objectives

- Describe the importance of early nutrition in premature infants; Define recommendations and guidelines while understanding clinical practice challenges for key nutrition requirements in premature infants
- Define the vitamin, trace element, and electrolyte needs and understand their importance to the premature infant within current guidelines
- Understand the complex compatibility and stability issues associated with parenteral nutrition (PN) that have the potential to impact safety; Discuss important considerations and challenges in the preparation and administration of PN and the general process and clinical outcomes with a standardized versus individualized approach to ordering PN
- Understand the importance and clinical differences between lipid emulsions through a review of the clinical evidence in parenteral nutrition in neonatal populations
- Learn the benefits, best practices and implementation strategies of integrating NUMETA G13E into clinical practice.

2021 iCAN EMEA Regional Neonatology - Agenda

Time	Activity	Speaker
16:00 –16:03	Welcome, Introductions, and Program Objectives	Baxter Medical Affairs
16:03 –16:30	Presentation 1* with discussion: Importance of Parenteral Nutrition in Feeding Premature Infants	Dr. Chris van den Akker
16:30 –17:00	Presentation 2* with discussion: Fluid, Electrolyte, and Micronutrient Needs in Preterm Infants	Dr. Chris van den Akker
17:00 –17:30	Presentation 3* with discussion: Safe Preparation and Delivery of Parenteral Nutrition	Mattias Paulsson
17:30 –18:00	Presentation 4* with discussion: Lipids: A Functional Nutrient for Growth <i>Program closes for countries where branded content presented in English is not allowed</i>	Dr. Chris van den Akker
18:00 –18:30	Presentation 5** with discussion: Practical PN: Integrating a Paediatric 3CB into Your Practice	Dr. Dirk Wackernagel

* The presentations delivered by the Speakers will contain a case study and audience response polling (or other interactive vehicle) that will be discussed throughout the day to increase engagement and simulate clinical practice.

** NUMETA G13E personal experience presentation from KOL Super User. Available for countries where branded content is allowed

Numeta G13E emulsion for infusion

COMPOSITION Three-chamber bag. Each bag contains a sterile non-pyrogenic combination of a glucose solution, a pediatric amino acids solution, with electrolytes, and a lipid emulsion. Numeta G13E: Container size 300 ml, 50% glucose solution: 80 ml, 5,9% amino acid solution with electrolytes: 160 ml, 12,5% lipid emulsion: 60 ml. **THERAPEUTICAL INDICATIONS** Numeta G13E is indicated for parenteral nutrition in preterm newborn infants when oral or enteral nutrition is not possible, insufficient or contraindicated. **POSODOLOGY** Numeta G13E: Maximal volume/kg/day of Numeta G13E with lipids 127,9 ml/kg and Numeta G13E without lipids 102,3 ml/kg. Max infusion rate [ml/kg/h] of Numeta G13E with lipids 6,4 ml/kg/h and of Numeta G13E without lipids 5,1 ml/kg/h. **ADMINISTRATION** Administered through a central vein. However, sufficient dilution of Numeta G13E with water for injection lowers the osmolarity and allows peripheral infusion. **CONTRAINDICATIONS** Numeta G13E without lipids: 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. Concomitant treatment with ceftriaxone even if separate infusion lines are used. Severe hyperglycaemia. Numeta G13E with lipids: Severe hyperlipidaemia, or severe disorders of lipid metabolism characterized by hyper triglyceridaemia. **UNDESIRABLE EFFECTS Clinical Trial and Post-marketing experience Adverse Reactions Metabolism and nutrition disorders. Common:** Hypophosphataemia, Hyperglycaemia, Hypercalcaemia, Hypertriglyceridaemia, Hyponatraemia. **Uncommon:** Hyperlipidaemia. Hepatobiliary disorders **Uncommon:** Cholestasis. Skin and subcutaneous tissue disorder **Not known:** Skin necrosis, Soft tissue injury. General disorders and administration site condition **Not known:** Extravasation. Fat overload syndrome: reduced ability to remove the lipids contained in Numeta G13E may result in a "fat overload syndrome" which may be caused by overdose and/or infusion rate higher than recommended and is associated with a sudden deterioration in the patient's clinical condition. It is characterized by 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]. **PRECAUTIONS 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. Latest approved SPC: 09/2020.

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.

This abbreviated summary of product characteristics

[SmPC] is intended for international use. Please note that it may differ from the licensed SmPC in the country where you are practicing.

Therefore, please always consult your country specific SPC available at www.produktresume.dk in Denmark; www.fimea.fi in Finland,

www.felleskatalogen.no in Norway or www.fass.se in Sweden.

NOR-CN12-210002 04/2021