FOR IMMEDIATE RELEASE

Media Contact
Colleen Weber, (224) 948-5353
media@baxter.com

Investor Contact
Clare Trachtman, (224) 948-3020

BAXTER ANNOUNCES U.S. FDA APPROVAL OF CLINIMIX AND CLINIMIX E WITH HIGHER PROTEIN FOR PATIENTS REQUIRING PARENTERAL NUTRITION

New formulations provide up to 60% more protein (amino acid) than current Clinimix formulations while delivering less dextrose[1]

DEERFIELD, Ill., SEPTEMBER 23, 2020 – Baxter International Inc. (NYSE: BAX), a global leader in clinical nutrition, today announced the U.S. Food and Drug Administration (FDA) approval of new formulations of **Clinimix** (amino acids in dextrose) Injections and **Clinimix E** (amino acids with electrolytes in dextrose and calcium) Injections. These new **Clinimix** formulations contain up to 80 g/L of amino acids, the highest protein in any multi-chamber bag available in the U.S.,[2] making it easier to reach patient protein targets while delivering less fluid and dextrose than provided by existing formulations.[3,4]

Parenteral nutrition (PN) is an intravenous administration of nutrition that plays an important role in helping reduce malnutrition and may include proteins (amino acids), carbohydrates, lipids (fats), electrolytes, vitamins and other trace elements. Guidelines from the Society of Critical Care Medicine (SCCM) and the American Society for Parenteral and Enteral Nutrition (ASPEN) recommend between 1.2 and 2.0 grams of protein per kilogram of body weight per day for a critically ill adult patient, and note that many patients may benefit from protein supplementation.[5] These patients may also have other nutritional considerations, like controlling blood glucose levels[4] and, in many cases, restricting fluid intake.[4]

"The introduction of **Clinimix** and **Clinimix E** formulations offers the highest protein in a multi-chamber bag in the U.S., allowing clinicians more flexibility in meeting their patients' nutritional goals," said Heather Knight, general manager of Baxter's U.S. hospital products business. "**Clinimix** and **Clinimix E with Higher Protein** complement Baxter's diverse portfolio of formulations that focus on helping improve care for critically ill patients."

In addition to these new higher protein formulations intended for patients with moderate to high protein needs, Baxter will continue to provide existing formulations of **Clinimix** and **Clinimix E** for

patients with lower protein needs. The approval of **Clinimix** and **Clinimix E with Higher Protein** follows the U.S. introduction of **Clinolipid** (20% Lipid Injectable Emulsion), the company's proprietary olive oil-based lipid emulsion. **Clinolipid,** with less soybean oil and more omega-9 fatty acid than other commercially available mixed lipid emulsions, provides an additional therapy option for use in PN for adults.

About Baxter's Clinical Nutrition Portfolio

Baxter provides innovative and accessible products and services designed to be used in different healthcare environments, including in the ICU and the hospital, nursing homes, clinics and in homes. In addition to supplying many essential ingredients necessary to create well-balanced formulations of a clinical nutrition regimen, the company also offers products like **Q-NRG+**, a metabolic monitoring device utilizing indirect calorimetry (IC) technology, launched in the U.S. earlier this year. IC is considered the "gold standard"[6] to accurately measure a patient's calorie needs, or resting energy expenditure (REE). These readings can help inform prescription and administration of nutrition therapy, which may include parenteral nutrition (PN), the intravenous administration of nutrients.

Clinimix and **Clinimix E with Higher Protein** (amino acid) are available in the United States now.

About Baxter

Every day, millions of patients and caregivers rely on Baxter's leading portfolio of critical care, nutrition, renal, hospital and surgical products. For more than 85 years, we've been operating at the critical intersection where innovations that save and sustain lives meet the healthcare providers that make it happen. With products, technologies and therapies available in more than 100 countries, Baxter's employees worldwide are now building upon the company's rich heritage of medical breakthroughs to advance the next generation of transformative healthcare innovations. To learn more, visit www.baxter.com and follow us on Twitter, LinkedIn and Facebook.

Rx Only. Please see accompanying full Prescribing Information for Clinimix and Clinimix E.

Important Risk Information for Clinimix and Clinimix E

Indication

Clinimix sulfite-free (Amino Acid in Dextrose) Injections and **Clinimix E** sulfite-free (Amino Acid with Electrolytes in Dextrose and Calcium) Injections are indicated as a source of calories and protein (and electrolytes for **Clinimix E**) for patients requiring parenteral nutrition when oral or enteral nutrition is not possible, insufficient, or contraindicated. **Clinimix** and **Clinimix E** may be used to treat negative nitrogen balance in patients.

Contraindications

Clinimix and **Clinimix E** Injections are contraindicated in patients with known hypersensitivity to one or more amino acids or dextrose; in patients with inborn errors of amino acid metabolism due to risk of severe metabolic and neurologic complications; and in patients with pulmonary edema or acidosis due to low cardiac output. In addition, **Clinimix E** is contraindicated in neonates (less than 28 days of age) receiving concomitant treatment with ceftriaxone, even if separate infusion lines are used, due to the risk of fatal ceftriaxone calcium salt precipitation in the neonate's bloodstream.

Warnings, Precautions and Adverse Reactions

Pulmonary vascular precipitates causing pulmonary vascular emboli and pulmonary distress have been reported in patients receiving parenteral nutrition. Excess addition of calcium and phosphate increases the risk of the formation of calcium phosphate precipitates. The solution should be inspected for precipitates before admixing, after admixing, and again before administration. If signs of pulmonary distress occur, stop the infusion and initiate a medical evaluation. Precipitation of ceftriaxone-calcium can occur when ceftriaxone is mixed with **Clinimix E**, in the same intravenous administration line. Do not administer ceftriaxone simultaneously with **Clinimix E** via a Y-site. Stop infusion immediately and treat patient accordingly if signs or symptoms of a hypersensitivity reaction develop. Monitor for signs and symptoms of early infections. Refeeding severely undernourished patients may result in refeeding syndrome. Thiamine deficiency and fluid retention may also develop. Monitor severely undernourished patients and slowly increase nutrient intakes. **Clinimix** and **Clinimix E** solutions containing more than 5% dextrose have an osmolarity of ≥ 900 mOsm/L and must be infused through a central catheter. **Clinimix** and **Clinimix E** contain no more than 25 mcg/L of aluminum which may reach toxic levels with prolonged administration in patients with renal impairment. Preterm infants are at greater risk because their kidneys are immature, and they require large amounts of calcium and phosphate solutions which contain aluminum. Patients with renal impairment, including preterm infants, who receive parenteral levels of aluminum at greater than 4 to 5 mcg/kg/day, accumulate aluminum at levels associated with central nervous system and bone toxicity. Tissue loading may occur at even lower rates of administration. Parenteral Nutrition Associated Liver Disease (PNALD) has been reported in patients who receive parenteral nutrition for extended periods of time, especially preterm infants. If **Clinimix** and **Clinimix E** treated patients develop liver test abnormalities, consider discontinuation or dosage reduction. Use **Clinimix** and **Clinimix E** with caution in patients with cardiac insufficiency or renal impairment due to increased risk of electrolyte and fluid volume imbalance. Monitor renal and liver function parameters, ammonia levels, fluid and electrolyte status, serum osmolarity, blood glucose, blood count and coagulation parameters throughout treatment. In situations of severely elevated electrolyte levels, stop **Clinimix** and **Clinimix E** until levels have been corrected. Adverse reactions include diuresis, extravasation, glycosuria, hyperglycemia, and hyperosmolar coma.

Dosage and Administration

See full prescribing information for information on preparation, administration, instructions for use, dosing considerations, including the recommended dosage in adults and pediatrics, and dosage modifications in patients with renal impairment.

Rx Only. Please click here for full prescribing information for **Clinolipid**, including Boxed Warning

Important Safety Information for Clinolipid

Clinolipid 20% (Lipid Injectable Emulsion) for Intravenous Use Indication

Clinolipid injection is indicated in adults for providing a source of calories and essential fatty acids for parenteral nutrition when oral or enteral nutrition is not possible, insufficient, or contraindicated.

Limitations of Use

Clinolipid injection is not indicated for use in pediatric patients because there is insufficient data to demonstrate that **Clinolipid** injection provides sufficient amounts of essential fatty acids in this population.

The omega-3: omega-6 fatty acid ratio in **Clinolipid** injection has not been shown to improve clinical outcomes compared to other intravenous lipid emulsions.

Important Risk Information

WARNING: DEATH IN PRETERM INFANTS

Deaths in preterm infants after infusion of intravenous lipid emulsions have been reported in medical literature.

Autopsy findings included intravascular fat accumulation in the lungs.

Preterm infants and low birth weight infants have poor clearance of intravenous lipid emulsion and increased free fatty acid plasma levels following lipid emulsion infusion.

The use of **Clinolipid** injection is contraindicated in patients with the following:

- Known hypersensitivity to egg or soybean proteins, the lipid emulsion and/or excipients.
- Severe hyperlipidemia or severe disorders of lipid metabolism

Stop infusion immediately and treat patient accordingly if signs or symptoms of a hypersensitivity or allergic reaction develop.

Monitor for signs and symptoms of fat overload, essential fatty acid deficiency (EFAD) and infections including laboratory test results (including leukocytosis and hyperglycemia) and frequent checks of the parenteral access device.

Carefully monitor severely undernourished patients and slowly increase their nutrient intakes, while avoiding overfeeding, to prevent refeeding complications.

Frequent clinical and laboratory determinations are necessary throughout treatment. Monitor fluid status closely in patients with pulmonary edema or heart failure.

Content of vitamin K may counteract anticoagulant activity.

Clinolipid injection contains no more than 25 mcg/L of aluminum. There is an increased aluminum toxicity risk in patients with impaired kidney function, including preterm infants.

Parenteral Nutrition Associated Liver Disease (PNALD) has been reported in patients who receive parenteral nutrition for extended periods of time, especially preterm infants. Monitor liver function tests. If patients develop liver test abnormalities consider discontinuation or dose reduction.

Reduce dose of **Clinolipid** injection and monitor serum triglyceride levels in patients with serum triglyceride concentrations above 400 mg/dL.

The most common (5%) adverse drug reactions reported during **Clinolipid** injection clinical trials were nausea and vomiting, hyperlipidemia, hyperglycemia, hypoproteinemia and abnormal liver function tests.

QNRG+: **Rx Only**: For safe and proper use of this device, please refer to User's Manual.

This release includes forward-looking statements concerning Baxter, Clinimix, Clinimix E, Clinolipid, and Q-NRG+, including all indications thereof and potential benefits associated with their use and anticipated availability. The statements are based on assumptions about many important factors, including the following, which could cause actual results to differ materially from those in the forward-looking statements: satisfaction of regulatory and other requirements; actions of regulatory bodies and other governmental authorities; product quality, manufacturing or supply issues; patient safety issues; changes in law and regulations; and other risks identified in Baxter's most recent filing on Form 10-K and other SEC filings, all of which are available on Baxter's website. Baxter does not undertake to update its forward-looking statements.

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[1] When comparing formulations 8/10 and 8/14 to formulations 5/15 and 5/20.
[2] KABIVEN- dextrose, soybean oil, electrolytes, lysine, phenylalanine, leucine, valine, threonine, methionine, isoleucine, tryptophan, alanine, arginine, glycine, proline, histidine, glutamic acid, serine, aspartic acid and tyrosine injection, emulsion. (2019, January 9). Retrieved September 2020, from https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=afeb4837-a759-4484-a76e-e04611c459e7.
[3] Clinimix E (amino acids with electrolytes in dextrose with calcium) injection, for intravenous use, September 2020.
[4] Clinimix (amino acids in dextrose) injection, for intravenous use, September 2020.
[5] McClave S, et al. Guidelines for the Provision and Assessment of Nutrition Support Therapy in the Adult Critically Ill Patient: Society of Critical Care Medicine (SCCM) and American Society for Parenteral and Enteral Nutrition (A.S.P.E.N.). JPEN. 2016;40:159-211.
[6] Frankenfield D, Ashcraft C. Estimating Energy Needs in Nutrition Support Patients. Journal of Parenteral and Enteral Nutrition. 35(5). 2011. 563-570.