

Mix with human milk or human milk-derived sources

# Prolact CR®

## 10 mL Human Milk Caloric Fortifier (Human, Pasteurized)

Contains 2.6 kcal/mL

To be used under the supervision of a physician. Intended for premature/low-birth-weight infants fed human milk.

### Product Description

Prolact CR® human milk caloric fortifier is pasteurized human milk cream derived from human milk. It is composed of approximately 88% fat, 11% carbohydrate, and 1% protein to provide 2.6 kcal/mL. It contains no added minerals.

- Nutritionally incomplete. Infant will require additional vitamins and iron added separately from the product.
- Available frozen in 30 mL bottles containing 10 mL of product (4 bottles per unit carton).

### Ingredients

Human milk cream and human milk ultrafiltration permeate.

### Storage

Store at -20°C or colder until ready to thaw for use.

### Directions for Thawing

**Under no circumstances should the product be defrosted or warmed in a microwave.**

Recommended method of thawing is refrigeration (2°C to 8°C).

- Place unopened (frozen) bottle in refrigerator.
- Once the thawing process begins, administer within 48 hours; discard any unused portion.
- Do not refreeze. Keep refrigerated until used.

### Preparation Instructions

**Always maintain aseptic technique when preparing and handling human milk. DO NOT ADD WATER.**

1. After the bottle has been properly thawed (see above), remove the cap from bottle.
2. Swirl gently prior to preparing each aliquot; DO NOT SHAKE.
3. Use Prolact CR as directed at the physician's discretion. Prolact CR contains 2.6 kcal/mL.
4. Gently swirl bottle to mix; DO NOT SHAKE.
5. When the steps above are completed, the product is ready for use.
6. Do not refreeze. Keep refrigerated (2°C to 8°C) until used.

### Use of Product

Initiation of enteral feedings and advancement feeding rates should be individualized based on the infant's weight, age, and clinical status.

Optimally, MOM and/or donor milk should provide a minimum of 20 kcal/fl oz. However, data show that 65% of the time, term MOM is less than 20 kcal/fl oz. Fat has been found to be the most variable component in human milk, accounting for decreases in energy density.<sup>1</sup> Due to the variability in human milk, fortification may result in suboptimal nutritional intakes and growth.<sup>1</sup> Prolact CR human milk caloric fortifier is the only completely human solution created to add calories for infants receiving low caloric content from MOM or donor human milk, without a substantial increase in volume or introduction of a non-human milk-based nutritional product. Prolact CR fortifier, when used as intended, can improve growth rates in premature infants.<sup>2</sup>

### An Exclusive Human Milk Diet (EHMD)

**An EHMD is achieved when 100% of the protein, fat, and carbohydrates are derived solely from human milk.** If MOM cannot be assured to provide a minimum of 20 kcal/fl oz, Prolact CR human milk caloric fortifier can be used. Prolact CR fortifier is a pasteurized formulation of human milk cream (derived from donor human milk) that can be added to MOM to increase the caloric content. If donor milk cannot be assured to provide 20 kcal/fl oz, consider the use of Prolact HM® pasteurized donor human milk, which is standardized to deliver a minimum of 20 kcal/fl oz.

A prospective, noninferiority, randomized study showed that very-low-birth-weight premature infants who received human milk-derived cream, in addition to fortified human milk as part of an EHMD, had improved weight and length velocity.<sup>2</sup> Further, a secondary analysis of data from the study found that infants who received the human milk-derived cream supplement had a significantly earlier post-menstrual age at discharge and trended toward a decreased length of stay when compared to those who did not receive the cream supplement.<sup>3</sup>

An EHMD, consisting of human milk and Prolact+ H<sup>2</sup>MF human milk-based human milk fortifier, has been clinically proven to reduce the odds of developing necrotizing enterocolitis (NEC), surgery related to NEC, sepsis, and mortality in premature infants weighing 500 to 1250 g at birth.<sup>4,5,6</sup>

A combined analysis of two randomized clinical studies demonstrated a dose-related effect of cow milk-based milk intake in increasing negative patient outcomes for premature infants <1250 g. For every 10% increase in the volume of milk containing cow milk, the risk of NEC, surgical NEC, and sepsis increased.<sup>6</sup>

Only Prolacta offers a full line of human milk-based products for providing an EHMD. An EHMD may require additional nutrients. No commercially available human milk fortifier (HMF) can be guaranteed to provide the full and necessary nutritional needs of every preterm infant.

### Safety Information

**Abruptly transitioning the infant's diet from this product to cow milk-based nutrition could result in feeding intolerance or gastrointestinal complications. To obtain a copy of Prolacta's Feeding Transition From an Exclusive Human Milk Diet, please contact your Prolacta Representative.**

#### References:

1. Wajick K, et al. Macronutrient analysis of a nationwide sample of donor breast milk. *J Am Diet Assoc.* January 2009;109:137-140. doi:10.1016/j.jada.2008.10.008.
2. Hair AB, Blanco CL, Moreira AG, et al. Randomized trial of human milk cream as a supplement to standard fortification of an exclusive human milk-based diet in infants 750-1250 g birth weight. *J Pediatr.* 2014;165(5):915-920. doi:10.1016/j.jpeds.2014.07.005.
3. Hair AB, Bergner EM, Lee ML, et al. Premature infants 750-1,250 g birth weight supplemented with a novel human milk-derived cream are discharged sooner. *Breastfeed Med.* 2016;11(3):133-137. doi:10.1089/bfm.2015.0166.
4. Sullivan S, Schanler RJ, Kim JH, et al. An exclusively human milk-based diet is associated with a lower rate of necrotizing enterocolitis than a diet of human milk and bovine milk-based products. *J Pediatr.* 2010;156(4):562-567.e1. doi:10.1016/j.jpeds.2009.10.040.
5. Cristofalo EA, Schanler RJ, Blanco CL, et al. Randomized trial of exclusive human milk versus preterm formula diets in extremely premature infants. *J Pediatr.* 2013;163(6):1592-1595.e1. doi:10.1016/j.jpeds.2013.07.011.
6. Abrams SA, Schanler RJ, Lee ML, Reichtman DJ. Greater mortality and morbidity in extremely preterm infants fed a diet containing cow milk protein products. *Breastfeed Med.* 2014;9(6):281-285. doi:10.1089/bfm.2014.0024.

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