

# 10 mL

Mix with  
human milk

# Prolact CR<sup>®</sup>

**Human Milk Caloric Fortifier (Human, Pasteurized)**

Contains 2.5 Cal/mL (74 Cal/fl oz)

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

## Product Description

Prolact CR<sup>®</sup> human milk caloric fortifier is pasteurized human milk cream derived from human milk. It is composed of approximately 25% fat and provides at least 2.5 Cal/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. Prepare according to one of the following mixing instructions:

- A.** If using a commercial human milk analyzer or creatocrit, follow the manufacturer's instructions for operation. Based on the measured caloric content of mother's own milk (MOM) or donor milk, follow the instructions in Table 1 to formulate 100 mL of human milk with Prolact CR fortifier.

Table 1: Prolact CR Fortifier Mixing Ratios Using a Commercial Milk Analyzer or Creatocrit

| Cal/100 mL | or | Cal/fl oz | Human Milk (mL) | + | Prolact CR (mL) | = | Total Volume (mL) |
|------------|----|-----------|-----------------|---|-----------------|---|-------------------|
| 64 - 67.9  |    | 19 - 20   | 98              |   | 2               |   | 100               |
| 61 - 63.9  |    | 18 - 18.9 | 96              |   | 4               |   | 100               |
| 57 - 60.9  |    | 17 - 17.9 | 94              |   | 6               |   | 100               |
| 54 - 56.9  |    | 16 - 16.9 | 93              |   | 7               |   | 100               |
| 51 - 53.9  |    | 15 - 15.9 | 91              |   | 9               |   | 100               |
| 47 - 50.9  |    | 14 - 14.9 | 90              |   | 10              |   | 100               |

## Preparation Instructions (continued)

- B.** If a commercial milk analyzer or creatocrit is not being used, use Prolact CR fortifier as directed at the physician's discretion. Each mL of Prolact CR fortifier adds 2.5 Calories to the feeding solution.
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.<sup>1</sup>

Optimally, MOM and/or donor milk should provide a minimum of 20 Cal/fl oz. However, data show that 65% of the time, term MOM is less than 20 Cal/fl oz. Fat has been found to be the most variable component in human milk, accounting for decreases in energy density.<sup>2</sup> Due to the variability in human milk, fortification may result in suboptimal nutritional intakes and growth.<sup>2</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>3</sup>

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## 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 Cal/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 Cal/fl oz, consider the use of Prolact HM<sup>®</sup> pasteurized donor human milk, which is standardized to deliver a minimum of 20 Cal/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>3</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>4</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>5,6,7</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>7</sup>

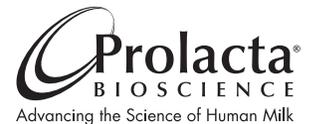
Only Prolacta offers a full line of human milk-based products for providing an EHMD. An EHMD may require additional nutrients. No commercially available human milk fortifier (HMF) can be guaranteed to provide the full and necessary nutritional needs of every preterm infant.

## 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 Clinical Guideline for Feeding Transition, please contact your Prolacta Representative.**

## Manufactured By

Prolacta Bioscience, Inc.  
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### References:

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