

10 mL
Mix with
human milk

Humavant® CR

Human Milk Caloric Fortifier (Human, Pasteurized)
Food for special medical purpose

For the dietary management of premature/low-birth-weight infants fed human milk. Product must be used under medical supervision. Not for parenteral use.

Product Description

Humavant® CR human milk caloric fortifier is pasteurized human milk cream derived from human milk. It is composed of approximately 25% fat and provides at least 2.6 kcal (11 kJ) / 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 creatamocrit, 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 Humavant® CR fortifier.

Table 1: Humavant® CR Fortifier Mixing Ratios Using a Commercial Milk Analyzer or Creatamocrit

kcal/100 mL	Human Milk (mL)	+ Humavant CR (mL)	= Total Volume (mL)
64 - 67.9	98	2	100
61 - 63.9	96	4	100
57 - 60.9	94	6	100
54 - 56.9	93	7	100
51 - 53.9	91	9	100
47 - 50.9	90	10	100

References:

1. Texas Children's Hospital. *Pediatric Nutrition Reference Guide*. 10th ed. Houston, TX: Texas Children's Hospital; 2013:156.
2. Wojcik K, et al. Macronutrient analysis of a nationwide sample of donor breast milk. *J Am Diet Assoc*. 2009;109:137-140. doi:10.1016/j.jada.2008.10.008

Preparation Instructions (continued)

- B. If a commercial milk analyzer or creatamocrit is not being used, use Humavant® CR fortifier as directed at the physician's discretion. Each mL of Humavant® CR fortifier adds 2.6 kcal (11 kJ) / mL 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.¹

Optimally, MOM and/or donor milk should provide a minimum of 0.67 kcal (3 kJ) / mL. However, data show that 65% of the time, term MOM is less than 0.67 kcal (3 kJ) / mL. Fat has been found to be the most variable component in human milk, accounting for decreases in energy density.² Due to the variability in human milk, fortification may result in suboptimal nutritional intakes and growth.² Humavant® 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.

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 0.67 kcal (3 kJ) / mL, Humavant® CR human milk caloric fortifier can be used. Humavant® 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 0.67 kcal (3 kJ) / mL, consider the use of Humavant® HM pasteurized donor human milk, which is standardized to deliver a minimum of 0.67 kcal (3 kJ) / mL.

Only Prolacta Bioscience 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 Bioscience's *Clinical Guideline for Feeding Transition*, please contact your Prolacta Bioscience Representative.

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