

20 mL

Must be mixed with
80 mL human milk

Prolact+4 H²MF[®]

Human Milk Fortifier (Human, Pasteurized)

When mixed, adds 4 Calories per fl oz.

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

Product Description

Prolact+4 H²MF human milk fortifier (HMF) is the only HMF made exclusively from 100% donor breast milk. The product is a human milk-based, concentrated, pasteurized, liquid HMF that helps provide essential calories, protein, and minerals to meet the nutritional needs of premature infants.

- Nutritionally incomplete. Infant will require additional vitamins and iron added separately from the product.
- Available frozen in 125 mL bottles containing 20 mL of product.

Ingredients

Human milk, contains less than 2% of the following: calcium glycerophosphate, calcium gluconate, sodium citrate, magnesium phosphate, calcium chloride, potassium citrate, calcium carbonate, zinc sulfate, cupric sulfate.

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 for 2-5 hours. Thaw time will vary by fortifier concentration. As the caloric value (volume) increases, the thaw time may take longer.
- Swirl gently to detect ice in the bottle. If ice is still present, return to the refrigerator for additional thaw time. Repeat until no ice is detected.
- Once the thawing process begins, administer within 48 hours.

Do not refreeze. Keep refrigerated until used.

Preparation Instructions

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

Each bottle of Prolact+4 H²MF fortifier contains 20 mL of fortifier and must be mixed with 80 mL of human milk (ratio 1:4).

- After the bottle has been properly thawed (see above), remove the cap from bottle.
- Add 80 mL of human milk (expressed breast milk or donor milk) into the Prolact+4 H²MF bottle to achieve a total volume of 100 mL.
- Gently swirl bottle to mix; DO NOT SHAKE. The product is now ready for use.
- Measure out the fortified milk using sterile syringes according to the feeding order.
- Label each syringe with patient identifier and refrigerate (2°C to 8°C) until administered.

References:

1. Texas Children's Hospital. *Pediatric Nutrition Reference Guide*. 10th ed. Houston, TX: Texas Children's Hospital; 2013:156.

2. Data on file.

3. 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.

4. 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.

5. Abrams SA, Schanler RJ, Lee ML, Rechtman DJ. Greater mortality and morbidity in extremely preterm infants fed a diet containing cow milk protein products. *Breastfeed Med*. 2014;9(6):281-285.

Use of Product

Initiation of enteral feedings and advancement rates should be individualized based on infant's weight, age, and clinical status.¹ Optimally, mother's milk and/or donor milk should provide a minimum of 20 Cal/fl oz. Calcium to phosphorus ratio supports intrauterine accretion rates.² When used under medical supervision, both protein and fat levels are appropriate to achieve adequate growth.

When mixed with 20 Cal/fl oz preterm human milk, Prolact+4 H²MF provides 82 Calories and 2.3 grams of protein per 100 mL of feeding solution. Nutrition monitoring is always required.

An Exclusive Human Milk Diet (EHMD)

An EHMD is achieved when 100% of the protein, fat, and carbohydrates are derived solely from human milk. Prolact+ H²MF fortifier is the first and only HMF derived from human milk as opposed to cow milk.

Prolact+ H²MF fortifier, when used as part of an EHMD, 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.^{3,4,5}

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.⁵

Only Prolacta offers a full line of human milk-based products for providing an EHMD. If mother's own milk 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 mother's milk to increase the caloric content to 20 Cal/fl oz. If donor milk cannot be assured to provide 20 Cal/fl oz, consider the use of Prolact HM[®] pasteurized donor human milk, which is standardized to deliver a minimum of 20 Cal/fl oz.

An EHMD may require additional nutrients. No commercially-available 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

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