

100 mL

Ready-to-Feed

Do not add water.
Do not add fortifier.
Do not mix with human milk.

Prolact RTF 28™

Human Milk–Based Premature Infant Formula

Contains at least 28 Calories per fl oz

To be used under supervision of a physician. Intended for premature/LBW infants who require a human milk-fortified diet.

Product Description

Prolact RTF 28™ premature infant formula is a ready-to-feed, human milk-based, fortified, pasteurized donor milk product that delivers standardized caloric content of at least 28 kcal/fl oz. The product contains protein, fat, and calories derived from pasteurized, donated, human milk. Essential minerals are added.

- Nutritionally incomplete. Infant will require additional vitamins and iron added separately from the product.
- Available frozen in 125 mL bottles containing 100 mL of product.

Ingredients

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

Each bottle of Prolact RTF 28 contains 100 mL of ready-to-feed human milk-based premature infant formula.

- After the bottle has been properly thawed (see above), remove the cap from bottle.
- 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. Mimouni FB, Mandel D, Lubetzky R, Senterre T. Calcium, phosphorus, magnesium and vitamin D requirements of the preterm infant. *World Rev Nutr Diet.* 2014;110:140-151. doi:10.1159/000358463 2. 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. 3. 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. 4. 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.

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Use of Product

Initiation of enteral feedings and advancement rates should be individualized based on infant's weight, age, and clinical status. Calcium to phosphorus ratio supports intrauterine accretion rates.¹ When used under medical supervision, both protein and fat levels are appropriate to achieve adequate growth.

Prolact RTF 28 provides 99 Calories and 2.9 grams of protein per 100 mL of feeding solution. Extreme caution should be taken when using Prolact RTF 28 at volumes above 150 mL/kg/day due to high protein intake. 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 RTF is the first and only ready-to-feed human milk-based premature infant formula derived from 100% human milk as opposed to cow milk.

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.^{2,3,4}

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.⁴

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) or premature infant formula 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.

Manufactured By

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Advancing the Science of Human Milk[®]