

10 mL

PremieLact[®]

Human Milk for Trophic Feeds (Pasteurized)

Product Description

PremieLact[®] is pasteurized human milk for trophic feeds. PremieLact may be used as the initial feeding of a 100% human milk diet when mother's own milk is unavailable. PremieLact delivers an average of 7.2 kcal (at least 20 kcal/fl oz) and 0.1 g of protein per 10 mL.

- Nutritionally incomplete. Infant may 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

Storage

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

Directions for Thawing

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

Remove bottle from freezer and label with date and time. Recommended method of thawing is refrigeration (2°C to 8°C).

- Place unopened (frozen) bottle in refrigerator.
- 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 of thawing or according to hospital policy regarding human milk - whichever time frame is shorter; 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.

- 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 milk using sterile syringes according to the feeding order.
- Label each syringe with patient identifier and refrigerate (2°C to 8°C) until administered.

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 kcal/fl oz. When used under medical supervision, both protein and fat levels are appropriate to achieve adequate growth.

An Exclusive Human Milk Diet (EHMD)

An EHMD is achieved when 100% of the protein, fat, and carbohydrates are derived solely from human milk. PremieLact, human milk for trophic feed, is formulated to deliver a minimum of 20 kcal/fl oz.

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. If mother's own milk 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 mother's milk to increase the caloric content to 20 kcal/fl oz. An EHMD may require additional nutrients.

Safety Information

PremieLact is 100% human milk. 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.

- All donors are screened for human immunodeficiency virus type 1 and type 2 (HIV-1/HIV-2), human T-lymphotropic virus type I and type II (HTLV-I/HTLV-II), hepatitis virus type B (HBV) and type C (HCV), and syphilis.
- All donor milk undergoes drug screening for drugs of abuse, nicotine, and their principle metabolites.
- Donor identity matching is performed on donated human milk using DNA fingerprinting.
- Each donation is tested using nucleic acids amplification testing (NAT) for pathogenic viruses and bacteria listed below:
 - Human immunodeficiency virus Type 1 and Type 2 (HIV-1/HIV-2)
 - Hepatitis virus Type B and Type C (HBV/HCV)
 - Zika virus (ZIKV)
 - Human T-lymphotropic virus Type I and Type II (HTLV-I/HTLV-II)
 - *Treponema pallidum*
 - *Mycobacterium tuberculosis*

Manufactured By

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References: 1. Texas Children's Hospital. *Guidelines for Acute Care of the Neonate*. 27th ed. Houston, TX: Texas Children's Hospital; 2019:188. 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.