

# 10 mL

Must be mixed with  
40 mL human milk

# Prolact+4 H<sup>2</sup>MF<sup>®</sup>

Human Milk Fortifier (Human, Pasteurized)

When mixed, adds at least 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 H<sup>2</sup>MF<sup>®</sup> 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 10 mL of product.

## Ingredients

Human milk, contains less than 2% of the following: Calcium Glycerophosphate, Potassium Citrate, Sodium Citrate, Sodium Chloride, Calcium Gluconate, Magnesium Phosphate, Calcium Chloride, 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 H<sup>2</sup>MF fortifier contains 10 mL of fortifier and must be mixed with 40 mL of human milk (ratio 1:4).

- After the bottle has been properly thawed (see above), remove the cap from bottle.
- Add 40 mL of human milk (expressed breast milk or donor milk) into the Prolact+4 H<sup>2</sup>MF bottle to achieve a total volume of 50 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. 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. Optimally, mother's milk and/or donor milk should provide a minimum of 20 kcal/fl oz. Calcium to phosphorus ratio supports intrauterine accretion rates.<sup>1</sup> When used under medical supervision, both protein and fat levels are appropriate to achieve adequate growth.

When mixed with 20 kcal/fl oz preterm human milk, Prolact+4 H<sup>2</sup>MF provides 42 Calories and 1.3 grams of protein per 50 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+ H<sup>2</sup>MF fortifier is the first and only HMF derived from human milk as opposed to cow milk.

Prolact+ H<sup>2</sup>MF 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.<sup>2,3,4</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>4</sup>

**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<sup>®</sup> 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. If donor milk cannot be assured to provide 20 kcal/fl oz, consider the use of Prolact HM<sup>®</sup> pasteurized donor human milk, which is standardized to deliver a minimum of 20 kcal/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 Feeding Transition From an Exclusive Human Milk Diet, please contact your Prolacta Representative.**

## Manufactured By

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 **Prolacta<sup>®</sup>**  
BIOSCIENCE  
Advancing the Science of Human Milk<sup>®</sup>

# 20 mL

Must be mixed with  
80 mL human milk

# Prolact+4 H<sup>2</sup>MF<sup>®</sup>

Human Milk Fortifier (Human, Pasteurized)

When mixed, adds at least 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 H<sup>2</sup>MF<sup>®</sup> 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, Potassium Citrate, Sodium Citrate, Sodium Chloride, Calcium Gluconate, Magnesium Phosphate, Calcium Chloride, 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 H<sup>2</sup>MF 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 H<sup>2</sup>MF 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. 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.

## Use of Product

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

When mixed with 20 kcal/fl oz preterm human milk, Prolact+4 H<sup>2</sup>MF provides 83 Calories and 2.5 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+ H<sup>2</sup>MF fortifier is the first and only HMF derived from human milk as opposed to cow milk.

Prolact+ H<sup>2</sup>MF 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.<sup>2,3,4</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>4</sup>

**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<sup>®</sup> 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. If donor milk cannot be assured to provide 20 kcal/fl oz, consider the use of Prolact HM<sup>®</sup> pasteurized donor human milk, which is standardized to deliver a minimum of 20 kcal/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 Feeding Transition From an Exclusive Human Milk Diet, please contact your Prolacta Representative.**

## Manufactured By

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# 15 mL

Must be mixed with  
35 mL human milk

# Prolact+6 H<sup>2</sup>MF<sup>®</sup>

Human Milk Fortifier (Human, Pasteurized)

When mixed, adds at least 6 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+6 H<sup>2</sup>MF<sup>®</sup> 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 15 mL of product.

## Ingredients

Human milk, contains less than 2% of the following: Calcium Glycerophosphate, Potassium Citrate, Sodium Citrate, Calcium Chloride, Calcium Gluconate, Sodium Chloride, Magnesium Phosphate, 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+6 H<sup>2</sup>MF fortifier contains 15 mL of fortifier and must be mixed with 35 mL of human milk (ratio 3:7).

- After the bottle has been properly thawed (see above), remove the cap from bottle.
- Add 35 mL of human milk (expressed breast milk or donor milk) into the Prolact+6 H<sup>2</sup>MF bottle to achieve a total volume of 50 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. 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.

## Use of Product

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

When mixed with 20 kcal/fl oz preterm human milk, Prolact+6 H<sup>2</sup>MF provides 45 Calories and 1.5 grams of protein per 50 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+ H<sup>2</sup>MF fortifier is the first and only HMF derived from human milk as opposed to cow milk.

Prolact+ H<sup>2</sup>MF 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.<sup>2,3,4</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>4</sup>

**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<sup>®</sup> 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. If donor milk cannot be assured to provide 20 kcal/fl oz, consider the use of Prolact HM<sup>®</sup> pasteurized donor human milk, which is standardized to deliver a minimum of 20 kcal/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 Feeding Transition From an Exclusive Human Milk Diet, please contact your Prolacta Representative.**

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# 30 mL

Must be mixed with  
70 mL human milk

# Prolact+6 H<sup>2</sup>MF<sup>®</sup>

## Human Milk Fortifier (Human, Pasteurized)

When mixed, adds at least 6 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+6 H<sup>2</sup>MF<sup>®</sup> 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 30 mL of product.

## Ingredients

Human milk, contains less than 2% of the following: Calcium Glycerophosphate, Potassium Citrate, Sodium Citrate, Calcium Chloride, Calcium Gluconate, Sodium Chloride, Magnesium Phosphate, 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+6 H<sup>2</sup>MF fortifier contains 30 mL of fortifier and must be mixed with 70 mL of human milk (ratio 3:7).

- After the bottle has been properly thawed (see above), remove the cap from bottle.
- Add 70 mL of human milk (expressed breast milk or donor milk) into the Prolact+6 H<sup>2</sup>MF 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. 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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SPI-0071 REV-0 10/20

## Use of Product

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

When mixed with 20 kcal/fl oz preterm human milk, Prolact+6 H<sup>2</sup>MF provides 91 Calories and 2.9 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+ H<sup>2</sup>MF fortifier is the first and only HMF derived from human milk as opposed to cow milk.

Prolact+ H<sup>2</sup>MF 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.<sup>2,3,4</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>4</sup>

**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<sup>®</sup> 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. If donor milk cannot be assured to provide 20 kcal/fl oz, consider the use of Prolact HM<sup>®</sup> pasteurized donor human milk, which is standardized to deliver a minimum of 20 kcal/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 Feeding Transition From an Exclusive Human Milk Diet, please contact your Prolacta Representative.**

## Manufactured By

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# 40 mL

Must be mixed with  
60 mL human milk

# Prolact+8 H<sup>2</sup>MF<sup>®</sup>

Human Milk Fortifier (Human, Pasteurized)

When mixed, adds at least 8 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+8 H<sup>2</sup>MF<sup>®</sup> 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 40 mL of product.

## Ingredients

Human milk, contains less than 2% of the following: Calcium Glycerophosphate, Potassium Citrate, Sodium Citrate, Calcium Chloride, Calcium Gluconate, Sodium Chloride, Magnesium Phosphate, 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+8 H<sup>2</sup>MF fortifier contains 40 mL of fortifier and must be mixed with 60 mL of human milk (ratio 2:3).

- After the bottle has been properly thawed (see above), remove the cap from bottle.
- Add 60 mL of human milk (expressed breast milk or donor milk) into the Prolact+8 H<sup>2</sup>MF 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. 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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SPI-0072 REV-0 10/20

## Use of Product

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

When mixed with 20 kcal/fl oz preterm human milk, Prolact+8 H<sup>2</sup>MF provides 98 Calories and 3.4 grams of protein per 100 mL of feeding solution. Extreme caution should be taken when using Prolact+8 H<sup>2</sup>MF fortified milk 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+ H<sup>2</sup>MF fortifier is the first and only HMF derived from human milk as opposed to cow milk.

Prolact+ H<sup>2</sup>MF 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.<sup>2,3,4</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>4</sup>

**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<sup>®</sup> 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. If donor milk cannot be assured to provide 20 kcal/fl oz, consider the use of Prolact HM<sup>®</sup> pasteurized donor human milk, which is standardized to deliver a minimum of 20 kcal/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 Feeding Transition From an Exclusive Human Milk Diet, please contact your Prolacta Representative.**

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Advancing the Science of Human Milk<sup>®</sup>

**50 mL**  
Must be mixed with  
50 mL human milk

# Prolact+10 H<sup>2</sup>MF<sup>®</sup>

Human Milk Fortifier (Human, Pasteurized)

When mixed, adds at least 10 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+10 H<sup>2</sup>MF<sup>®</sup> 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 50 mL of product.

## Ingredients

Human milk, contains less than 2% of the following: Calcium Glycerophosphate, Potassium Citrate, Sodium Citrate, Sodium Chloride, Calcium Chloride, Calcium Gluconate, Magnesium Phosphate, 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+10 H<sup>2</sup>MF fortifier contains 50 mL of fortifier and must be mixed with 50 mL of human milk (ratio 1:1).

- After the bottle has been properly thawed (see above), remove the cap from bottle.
- Add 50 mL of human milk (expressed breast milk or donor milk) into the Prolact+10 H<sup>2</sup>MF 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. 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.

## Use of Product

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

When mixed with 20 kcal/fl oz preterm human milk, Prolact+10 H<sup>2</sup>MF provides 105 Calories and 3.8 grams of protein per 100 mL of feeding solution. Extreme caution should be taken when using Prolact+10 H<sup>2</sup>MF fortified milk 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+ H<sup>2</sup>MF fortifier is the first and only HMF derived from human milk as opposed to cow milk.

Prolact+ H<sup>2</sup>MF 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.<sup>2,3,4</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>4</sup>

**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<sup>®</sup> 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. If donor milk cannot be assured to provide 20 kcal/fl oz, consider the use of Prolact HM<sup>®</sup> pasteurized donor human milk, which is standardized to deliver a minimum of 20 kcal/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 Feeding Transition From an Exclusive Human Milk Diet, please contact your Prolacta Representative.**

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# 10 mL

## Ready-to-Feed

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

# Prolact RTF 24™

## Human Milk-Based Premature Infant Formula

### Contains at least 24 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 24™ premature infant formula is a ready-to-feed, human milk-based, fortified, pasteurized donor milk product that delivers standardized caloric content of at least 24 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 30 mL bottles containing 10 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 24 contains 10 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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SPI-0077 REV-0 10/20

## 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.<sup>1</sup> When used under medical supervision, both protein and fat levels are appropriate to achieve adequate growth.

Prolact RTF 24 provides 8.5 Calories and 0.24 grams of protein per 10 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 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.<sup>2,3,4</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>4</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) 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.**

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# 100 mL

## Ready-to-Feed

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

# Prolact RTF 24™

## Human Milk-Based Premature Infant Formula

### Contains at least 24 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 24™ premature infant formula is a ready-to-feed, human milk-based, fortified, pasteurized donor milk product that delivers standardized caloric content of at least 24 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 24 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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SPI-0074 REV-0 10/20

## 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.<sup>1</sup> When used under medical supervision, both protein and fat levels are appropriate to achieve adequate growth.

Prolact RTF 24 provides 85 Calories and 2.4 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 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.<sup>2,3,4</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>4</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) 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.**

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# 100 mL

## Ready-to-Feed

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

# Prolact RTF 26™

## Human Milk-Based Premature Infant Formula

### Contains at least 26 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 26™ premature infant formula is a ready-to-feed, human milk-based, fortified, pasteurized donor milk product that delivers standardized caloric content of at least 26 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 26 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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SPI-0075 REV-0 10/20

## 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.<sup>2</sup> When used under medical supervision, both protein and fat levels are appropriate to achieve adequate growth.

Prolact RTF 26 provides 92 Calories and 2.7 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 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.<sup>2,3,4</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>4</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) 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.**

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# 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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SPI-0076 REV-0 10/20

## 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.<sup>1</sup> 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.<sup>2,3,4</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>4</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) 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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Mix with human milk or human milk-derived sources

# Prolact CR<sup>®</sup>

10 mL Human Milk Caloric Fortifier (Human, Pasteurized)

Contains 2.6 kcal/mL

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 88% fat, 11% carbohydrate, and 1% protein to provide 2.6 kcal/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. Use Prolact CR as directed at the physician's discretion. Prolact CR contains 2.6 kcal/mL.
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.

Optimally, MOM and/or donor milk should provide a minimum of 20 kcal/fl oz. However, data show that 65% of the time, term MOM is less than 20 kcal/fl oz. Fat has been found to be the most variable component in human milk, accounting for decreases in energy density.<sup>1</sup> Due to the variability in human milk, fortification may result in suboptimal nutritional intakes and growth.<sup>1</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>2</sup>

## 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 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 MOM to increase the caloric content. If donor milk cannot be assured to provide 20 kcal/fl oz, consider the use of Prolact HM<sup>®</sup> pasteurized donor human milk, which is standardized to deliver a minimum of 20 kcal/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>2</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>3</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>4,5,6</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>6</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 Feeding Transition From an Exclusive Human Milk Diet, please contact your Prolacta Representative.**

### References:

1. Wajick K, et al. Macronutrient analysis of a nationwide sample of donor breast milk. *J Am Diet Assoc.* January 2009;109:137-140. doi:10.1016/j.jada.2008.10.008.
2. Hair AB, Blanco CL, Moreira AG, et al. Randomized trial of human milk cream as a supplement to standard fortification of an exclusive human milk-based diet in infants 750-1250 g birth weight. *J Pediatr.* 2014;165(5):915-920. doi:10.1016/j.jpeds.2014.07.005.
3. Hair AB, Bergner EM, Lee ML, et al. Premature infants 750-1,250 g birth weight supplemented with a novel human milk-derived cream are discharged sooner. *Breastfeed Med.* 2016;11(3):133-137. doi:10.1089/bfm.2015.0166.
4. 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.e1. doi:10.1016/j.jpeds.2009.10.040.
5. 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.e1. doi:10.1016/j.jpeds.2013.07.011.
6. Abrams SA, Schanler RJ, Lee ML, Reichtman DJ. Greater mortality and morbidity in extremely preterm infants fed a diet containing cow milk protein products. *Breastfeed Med.* 2014;9(6):281-285. doi:10.1089/bfm.2014.0024.

## Distributed By

Prolacta Bioscience, Inc.  
City of Industry, CA 91746, USA  
www.prolacta.com  
1.888.776.5228



US

# 10 mL

# PremieLact<sup>®</sup>

## Human Milk for Trophic Feeds (Pasteurized)

### Product Description

PremieLact<sup>®</sup> 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.<sup>1</sup>

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.<sup>2,3,4</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>4</sup>

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<sup>®</sup> 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.

118 mL  
(4 fl oz)

# Prolact HM<sup>®</sup>

## Human Milk (Human, Pasteurized)

### Product Description

Prolact HM<sup>®</sup> is pasteurized human milk. Ideal for use alone or with Prolact+ H<sup>2</sup>MF<sup>®</sup> human milk fortifier when mother's own milk is unavailable. Prolact HM delivers an average of 72 kcal (at least 20 kcal/fl oz) and 1.0 g of protein per 100 mL.

- Nutritionally incomplete. Infant may require additional vitamins and iron added separately from the product.
- Available frozen in 125 mL bottles containing 118 mL (4 fl oz) of product.

### 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 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 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.<sup>1</sup> 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. Prolact HM, pasteurized donor human milk, is standardized 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.<sup>2,3,4</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>4</sup>

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<sup>®</sup> 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

**Prolact HM 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)
  - Human T-lymphotropic virus Type I and Type II (HTLV-I/HTLV-II)
  - Hepatitis virus Type B and Type C (HBV/HCV)
  - Zika virus (ZIKV)
  - *Treponema pallidum*
  - *Mycobacterium tuberculosis*

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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.