

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 10 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 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 H²MF 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. Texas Children's Hospital. Pediatric Nutrition Reference Guide. 10th ed. Houston, TX: Texas Children's Hospital; 2013:156. 2. Data on file.

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 41 Calories and 1.2 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+ 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

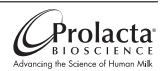
providing an EHMD. If mother's own milk cannot be assured to provide a minimum of 20 Cal/fl oz, Prolact CR® human milk caloric fortifier can be used. Prolact CR fortifier is a pasteurized formulation of human milk cream (derived from donor human milk) that can be added to mother's milk to increase the 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



^{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.

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 H^2MF 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.

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



^{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.

Prolact+6 H²MF[®]

Human Milk Fortifier (Human, Pasteurized)

When mixed, adds 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

15 mL

Must be mixed with

35 mL human milk

Prolact+6 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 15 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+6 H²MF 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 H²MF 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. Texas Children's Hospital. Pediatric Nutrition Reference Guide. 10th ed. Houston, TX: Texas Children's Hospital; 2013:156. 2. Data on file.

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+6 H²MF provides 45 Calories and 1.4 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+ 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

Prolacta Bioscience, Inc. City of Industry, CA 91746 www.prolacta.com 1(888) PROLACT



^{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.

Prolact+6 H²MF[®]

Human Milk Fortifier (Human, Pasteurized)

When mixed, adds 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

30 mL

Must be mixed with

70 mL human milk

Prolact+6 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 30 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+6 H²MF 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 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.

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+6 H²MF provides 89 Calories and 2.8 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



^{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.

Prolact+8 H²MF[®]

Human Milk Fortifier (Human, Pasteurized)

When mixed, adds 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

40 ml

Must be mixed with

60 mL human milk

Prolact+8 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 40 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+8 H²MF 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 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.

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+8 H²MF provides 97 Calories and 3.2 grams of protein per 100 mL of feeding solution. Extreme caution should be taken when using Prolact+8 H²MF 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+ 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

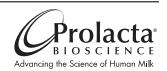
providing an EHMD. If mother's own milk cannot be assured to provide a minimum of 20 Cal/fl oz, Prolact CR® human milk caloric fortifier can be used. Prolact CR fortifier is a pasteurized formulation of human milk cream (derived from donor human milk) that can be added to mother's milk to increase the 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



^{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.

Prolact+10 H²MF[®]

Human Milk Fortifier (Human, Pasteurized)

When mixed, adds 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

50 ml

Must be mixed with

50 mL human milk

Prolact+10 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 50 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+10 H^2MF 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 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.

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+10 H²MF provides 104 Calories and 3.7 grams of protein per 100 mL of feeding solution. Extreme caution should be taken when using Prolact+10 H²MF 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+ 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.

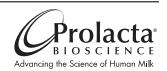
An EHMD may require additional nutrients. No commercially-available HMF can be guaranteed to provide the full and necessary nutritional needs of every preterm infant.

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.

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^{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

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.

^{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.

Prolact RTF 24 Human Milk-Based Premature Infant Formula

Ready-to-Feed Do not add water. Do not add fortifier. Do not mix with human milk.

Contains 24 Calories per fl oz.

k. To be used under supervision of a physician. Intended for very-low-birth-weight infants who require a human milk-fortified diet.

Product Description

Prolact RTF 24 premature infant formula is a ready-to-feed, human milkbased, fortified, pasteurized donor milk product that delivers standardized caloric content of 24 Cal/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.

Use of Product

Initiation of enteral feedings and advancement rates should be individualized based on infant's weight, age, and clinical status.¹ 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.

Prolact RTF 24 provides 81 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 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.^{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. 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 *Clinical Guideline for Feeding Transition*, please contact your Prolacta Representative.

Manufactured By



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.

Prolact RTF 26 Human Milk-Based Premature Infant Formula

Ready-to-Feed Do not add water. Do not add fortifier. Do not mix with human milk.

Contains 26 Calories per fl oz. To be used under supervision of a physician. Intended for very-low-birth-weight infants who require a human milk-fortified diet.

Product Description

Prolact RTF 26 premature infant formula is a ready-to-feed, human milkbased, fortified, pasteurized donor milk product that delivers standardized caloric content of 26 Cal/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.

Use of Product

Initiation of enteral feedings and advancement rates should be individualized based on infant's weight, age, and clinical status.¹ 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.

Prolact RTF 26 provides 88 Calories and 2.8 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.^{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. 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 *Clinical Guideline for Feeding Transition*, please contact your Prolacta Representative.

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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.

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

Prolact RTF 28 Human Milk-Based Premature Infant Formula

Ready-to-Feed Do not add water. Do not add fortifier. Do not mix with human milk.

Contains 28 Calories per fl oz. To be used under supervision of a physician. Intended for very-low-birth-weight infants who require a human milk-fortified diet.

Product Description

Prolact RTF 28 premature infant formula is a ready-to-feed, human milkbased, fortified, pasteurized donor milk product that delivers standardized caloric content of 28 Cal/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.

Use of Product

Initiation of enteral feedings and advancement rates should be individualized based on infant's weight, age, and clinical status.¹ 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.

Prolact RTF 28 provides 95 Calories and 3.2 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.^{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. 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 *Clinical Guideline for Feeding Transition*, please contact your Prolacta Representative.

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2. Data on file

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

^{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.

Prolact CR[®] Human Milk Caloric Fortifier (Human, Pasteurized)

Mix with human milk

Contains 2.5 Cal/mL (74 Cal/fl oz) To be used under the supervision of a physician. Intended for premature/low-birth-weight infants fed human milk.

Product Description

Prolact 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 2.5 Cal/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 creamatocrit, 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 Prolact CR fortifier.

Table 1: Prolact CR Fortifier Mixing Ratios Using a Commercial Milk Analyzer or Creamatocrit

Cal/100 mL or	Cal/fl oz	Human Milk · (mL)	+ Prolact CR = (mL)	Total Volume (mL)
64 - 67.9	19 - 20	98	2	100
61 - 63.9	18 - 18.9	96	4	100
57 - 60.9	17 - 17.9	94	6	100
54 - 56.9	16 - 16.9	93	7	100
51 - 53.9	15 - 15.9	91	9	100
47 - 50.9	14 - 14.9	90	10	100

Preparation Instructions (continued)

- B. If a commercial milk analyzer or creamatocrit is not being used, use Prolact CR fortifier as directed at the physician's discretion. Each mL of Prolact CR fortifier adds 2.5 Calories 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 20 Cal/fl oz. However, data show that 65% of the time, term MOM is less than 20 Cal/fl oz. 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 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.³

Prolact CR[®]

Mix with human milk Human Milk Caloric Fortifier (Human, Pasteurized) Contains 2.5 Cal/mL (74 Cal/fl oz) To be used under the supervision of a physician. Intended for premature/low-birth-weight infants fed human milk.

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 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 MOM to increase the caloric content. 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.

A prospective, noninferiority, randomized study showed that very-lowbirth-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.³ 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.⁴

An EHMD, consisting of human milk and Prolact+ H²MF 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.^{5,6,7}

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.⁷

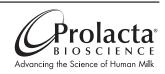
Only Prolacta offers a full line of human milk-based products for providing an EHMD. An EHMD may require additional nutrients. No commercially available human milk fortifier (HMF) can be guaranteed to provide the full and necessary nutritional needs of every preterm infant.

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 Clinical Guideline for Feeding Transition*, please contact your Prolacta Representative.

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References:

- 1. Texas Children's Hospital. Pediatric Nutrition Reference Guide. 10th ed. Houston, TX: Texas Children's Hospital; 2013:156
- 2. Woijcik 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
- 3. 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.
- 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.
 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/i.ioeds.2009.10.040.
- 6. Cristofia Ed. Schanler K. 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.
- 7. 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. doi:10.1089/bfm.2014.0024.

Product Description

PremieLact is pasteurized human milk for trophic feeds. PremieLact may be used as the initial feeding of a 100% human milk diet. PremieLact provides approximately 0.7 kcal per mL and contains no added minerals.

- Nutritionally incomplete. Infant may require additional vitamins and iron added separately from the product.
- Available frozen in 30mL bottles containing 10mL of product.

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.

Remove bottle from the freezer and label with date and time. Thaw product using either of the following methods:

- Refrigeration: (2°C to 8°C) Place unopened bottle in refrigerator. Once thawing process begins, administer within 48 hours. Do not refreeze, keep refrigerated until used.
- Rapid Thawing: Place bottle under lukewarm, running water, or place in a water bath. Do not submerge top of bottle. Warm only until product is thawed. Continued warming, or exposure to high temperatures, could result in undesirable changes to the product. Wipe outside of bottle with appropriate disinfectant to reduce the risk of contamination. Once thawing process begins, administer within 48 hours.

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 oral or ENFit[®] syringes according to the feeding order. Label each syringe with patient identifier and refrigerate (2°C to 8°C) until administered.

Safety Information

PremieLact is 100% human milk. Abrupt transitioning from this product to non-human milk derived nutrition in the infant's diet could result in feeding intolerance or GI complications. To obtain a copy of Prolacta's Clinical Guideline for Feeding Transition, please contact your Prolacta Representative.

- All donors are screened for HIV 1 & 2, HTLV I & II, HBV, HCV and syphilis.
- All donor milk undergoes drug screening for amphetamine, benzodiazepine, cocaine, marijuana (THC), methamphetamine, opiates, nicotine, oxycodone, oxymorphone and their principle metabolites.
- Donor identity matching is performed on donated breast milk using DNA fingerprinting.
- Pasteurization has repeatedly demonstrated a 10⁵ reduction of pathogenic viruses such as HIV, HBV and HCV. It has been shown to kill pathogenic bacteria such as *E. coli, S. aureus* and *Klebsiella* species at levels of 10¹⁵ or higher, the precise amount varying by strain and technique.
- HIV, also a marker virus for CMV, has been repeatedly demonstrated to inactivate during pasteurization.
- Pooled human breast milk is tested by PCR for the presence of HIV-1, HBV and HCV.

Ingredients

Human milk

Manufactured By



Product Description

Prolact HM is pasteurized human milk. When mother's milk is unavailable, this product should be used. It provides at least 67 kcal per 100mL and contains no added minerals.

- Nutritionally incomplete. Infant may require additional vitamins and iron added separately from the product.
- Available frozen in 125mL bottles containing 118.3mL (4 fl oz) of product.

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.

Remove bottle from the freezer and label with date and time. Thaw product using either of the following methods:

- Refrigeration: (2°C to 8°C) Place unopened bottle in refrigerator. Once thawing process begins, administer within 48 hours. Do not refreeze, keep refrigerated until used.
- Rapid Thawing: Place bottle under lukewarm, running water, or place in a water bath. Do not submerge top of bottle. Warm only until product is thawed. Continued warming, or exposure to high temperatures, could result in undesirable changes to the product. Wipe outside of bottle with appropriate disinfectant to reduce the risk of contamination. Once thawing process begins, administer within 48 hours.

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 oral or ENFit[®] syringes according to the feeding order. Label each syringe with patient identifier and refrigerate (2°C to 8°C) until administered.

Safety Information

Prolact HM is 100% human milk. Abrupt transitioning from this product to non-human milk derived nutrition in the infant's diet could result in feeding intolerance or GI complications. To obtain a copy of Prolacta's Clinical Guideline for Feeding Transition, please contact your Prolacta Representative.

- All donors are screened for HIV 1 & 2, HTLV I & II, HBV, HCV and syphilis.
- All donor milk undergoes drug screening for amphetamine, benzodiazepine, cocaine, marijuana (THC), methamphetamine, opiates, nicotine, oxycodone, oxymorphone and their principle metabolites.
- Donor identity matching is performed on donated breast milk using DNA fingerprinting.
- Pasteurization has repeatedly demonstrated a 10⁵ reduction of pathogenic viruses such as HIV, HBV and HCV. It has been shown to kill pathogenic bacteria such as *E. coli, S. aureus* and *Klebsiella* species at levels of 10¹⁵ or higher, the precise amount varying by strain and technique.
- HIV, also a marker virus for CMV, has been repeatedly demonstrated to inactivate during pasteurization.
- Pooled human breast milk is tested by PCR for the presence of HIV-1, HBV and HCV.

Ingredients

Human milk

Manufactured By

