

# 10 ml

Must be mixed with  
40 ml human milk

# Humavant™ +4

## Human Milk Fortifier (Human, Pasteurized)

### Food for special medical purposes

For the dietary management of premature/low-birth-weight infants fed human milk. Product must be used under medical supervision. Not for parenteral use.

## Product Description

Humavant™ +4 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**, calcium glycerophosphate, calcium gluconate, sodium citrate, potassium citrate, calcium 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 Humavant +4 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 Humavant +4 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.<sup>1</sup> Optimally, mother's milk and/or donor milk should provide a minimum of 0.67 kcal (3 kJ) /ml 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.

When mixed with 0.67 kcal (3 kJ) /ml preterm human milk, Humavant™ +4 provides 41 kcal (172 kJ) 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.** Humavant™ +4 fortifier is the first and only HMF derived from human milk as opposed to cow milk.

**Only Prolacta Bioscience 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 0.67 kcal (3 kJ) /ml, Humavant™ CR human milk caloric fortifier can be used. Humavant™ 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 0.67 kcal (3 kJ) /ml. If donor milk cannot be assured to provide 0.67 kcal (3 kJ) /ml, consider the use of Humavant™ HM pasteurized donor human milk, which is standardized to deliver a minimum of 0.67 kcal (3 kJ) /ml.

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

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# 20 ml

Must be mixed with  
80 ml human milk

# Humavant™ +4

## Human Milk Fortifier (Human, Pasteurized)

### Food for special medical purposes

For the dietary management of premature/low-birth-weight infants fed human milk. Product must be used under medical supervision. Not for parenteral use.

## Product Description

Humavant™ +4 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**, calcium glycerophosphate, calcium gluconate, sodium citrate, potassium citrate, calcium 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 Humavant™ +4 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 Humavant™ +4 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.<sup>1</sup> Optimally, mother's milk and/or donor milk should provide a minimum of 0.67 kcal (3 kJ) /ml. 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.

When mixed with 0.67 kcal (3 kJ) /ml preterm human milk, Humavant™ +4 provides 82 kcal (343 kJ) 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.** Humavant™ +4 fortifier is the first and only HMF derived from human milk as opposed to cow milk.

**Only Prolacta Bioscience 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 0.67 kcal (3 kJ) /ml, Humavant™ CR human milk caloric fortifier can be used. Humavant™ 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 0.67 kcal (3 kJ) /ml. If donor milk cannot be assured to provide 0.67 kcal (3 kJ) /ml, consider the use of Humavant™ HM pasteurized donor human milk, which is standardized to deliver a minimum of 0.67 kcal (3 kJ) /ml.

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

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# 15 ml

Must be mixed with  
35 ml human milk

# Humavant™ +6

## Human Milk Fortifier (Human, Pasteurized)

### Food for special medical purposes

For the dietary management of premature/low-birth-weight infants fed human milk. Product must be used under medical supervision. Not for parenteral use.

## Product Description

Humavant™ +6 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**, calcium glycerophosphate, calcium gluconate, sodium citrate, potassium citrate, calcium 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 Humavant™ +6 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 Humavant™ +6 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.<sup>1</sup> Optimally, mother's milk and/or donor milk should provide a minimum of 0.67 kcal (3 kJ) /ml. 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.

When mixed with 0.67 kcal (3 kJ) /ml preterm human milk, Humavant™ +6 provides 45 kcal (188 kJ) 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.** Humavant™ +6 fortifier is the first and only HMF derived from human milk as opposed to cow milk.

**Only Prolacta Bioscience 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 0.67 kcal (3 kJ) /ml, Humavant™ CR human milk caloric fortifier can be used. Humavant™ 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 0.67 kcal (3 kJ) /ml. If donor milk cannot be assured to provide 0.67 kcal (3 kJ) /ml, consider the use of Humavant™ HM pasteurized donor human milk, which is standardized to deliver a minimum of 0.67 kcal (3 kJ) /ml.

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

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# 40 ml

Must be mixed with  
60 ml human milk

# Humavant™ +8

## Human Milk Fortifier (Human, Pasteurized)

### Food for special medical purposes

For the dietary management of premature/low-birth-weight infants fed human milk. Product must be used under medical supervision. Not for parenteral use.

## Product Description

Humavant™ +8 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**, calcium glycerophosphate, sodium citrate, potassium citrate, calcium gluconate, calcium 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 Humavant™ +8 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 Humavant™ +8 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.<sup>1</sup> Optimally, mother's milk and/or donor milk should provide a minimum of 0.67 kcal (3 kJ) /ml. 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.

When mixed with 0.67 kcal (3 kJ) /ml preterm human milk, Humavant™ +8 provides 98 kcal (410 kJ) and 3.4 grams of protein per 100 ml of feeding solution. Extreme caution should be taken when using Humavant™ +8 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.** Humavant™ +8 fortifier is the first and only HMF derived from human milk as opposed to cow milk.

**Only Prolacta Bioscience 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 0.67 kcal (3 kJ) /ml, Humavant™ CR human milk caloric fortifier can be used. Humavant™ 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 0.67 kcal (3 kJ) /ml. If donor milk cannot be assured to provide 0.67 kcal (3 kJ) /ml, consider the use of Humavant™ HM pasteurized donor human milk, which is standardized to deliver a minimum of 0.67 kcal (3 kJ) /ml.

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

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# 30 ml

Must be mixed with  
70 ml human milk

# Humavant™ +6

## Human Milk Fortifier (Human, Pasteurized)

### Food for special medical purposes

For the dietary management of premature/low-birth-weight infants fed human milk. Product must be used under medical supervision. Not for parenteral use.

## Product Description

Humavant™ +6 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**, calcium glycerophosphate, calcium gluconate, sodium citrate, potassium citrate, calcium 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 Humavant™ +6 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 Humavant™ +6 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.<sup>1</sup> Optimally, mother's milk and/or donor milk should provide a minimum of 0.67 kcal (3 kJ) /ml. 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.

When mixed with 0.67 kcal (3 kJ) /ml preterm human milk, Humavant™ +6 provides 90 kcal (377 kJ) 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.** Humavant™ +6 fortifier is the first and only HMF derived from human milk as opposed to cow milk.

**Only Prolacta Bioscience 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 0.67 kcal (3 kJ) /ml, Humavant™ CR human milk caloric fortifier can be used. Humavant™ 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 0.67 kcal (3 kJ) /ml. If donor milk cannot be assured to provide 0.67 kcal (3 kJ) /ml, consider the use of Humavant™ HM pasteurized donor human milk, which is standardized to deliver a minimum of 0.67 kcal (3 kJ) /ml.

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

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# 40 ml

Must be mixed with  
60 ml human milk

# Humavant™ +8

## Human Milk Fortifier (Human, Pasteurized)

### Food for special medical purposes

For the dietary management of premature/low-birth-weight infants fed human milk. Product must be used under medical supervision. Not for parenteral use.

## Product Description

Humavant™ +8 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**, calcium glycerophosphate, sodium citrate, potassium citrate, calcium gluconate, calcium 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 Humavant™ +8 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 Humavant™ +8 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.<sup>1</sup> Optimally, mother's milk and/or donor milk should provide a minimum of 0.67 kcal (3 kJ) /ml. 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.

When mixed with 0.67 kcal (3 kJ) /ml preterm human milk, Humavant™ +8 provides 98 kcal (410 kJ) and 3.4 grams of protein per 100 ml of feeding solution. Extreme caution should be taken when using Humavant™ +8 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.** Humavant™ +8 fortifier is the first and only HMF derived from human milk as opposed to cow milk.

**Only Prolacta Bioscience 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 0.67 kcal (3 kJ) /ml, Humavant™ CR human milk caloric fortifier can be used. Humavant™ 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 0.67 kcal (3 kJ) /ml. If donor milk cannot be assured to provide 0.67 kcal (3 kJ) /ml, consider the use of Humavant™ HM pasteurized donor human milk, which is standardized to deliver a minimum of 0.67 kcal (3 kJ) /ml.

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

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BIOSCIENCE  
Advancing the Science of Human Milk

# 50 ml

Must be mixed with  
50 ml human milk

# Humavant™ +10

## Human Milk Fortifier (Human, Pasteurized)

### Food for special medical purposes

For the dietary management of premature/low-birth-weight infants fed human milk. Product must be used under medical supervision. Not for parenteral use.

## Product Description

Humavant™ +10 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**, calcium glycerophosphate, sodium citrate, potassium citrate, calcium gluconate, calcium chloride, magnesium phosphate, sodium 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 Humavant™ +10 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 Humavant™ +10 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.<sup>1</sup> Optimally, mother's milk and/or donor milk should provide a minimum of 0.67 kcal (3 kJ) /ml. 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.

When mixed with 0.67 kcal (3 kJ) /ml preterm human milk, Humavant™ +10 provides 105 kcal (439 kJ) and 3.8 grams of protein per 100 ml of feeding solution. Extreme caution should be taken when using Humavant™ +10 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.** Humavant™ +10 fortifier is the first and only HMF derived from human milk as opposed to cow milk.

**Only Prolacta Bioscience 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 0.67 kcal (3 kJ) /ml, Humavant™ CR human milk caloric fortifier can be used. Humavant™ 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 0.67 kcal (3 kJ) /ml. If donor milk cannot be assured to provide 0.67 kcal (3 kJ) /ml, consider the use of Humavant™ HM pasteurized donor human milk, which is standardized to deliver a minimum of 0.67 kcal (3 kJ) /ml.

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

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