

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.¹ 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.² 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

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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