

# 100% Human Milk-Based Neonatal Nutritional Products

## Improving the Standard of Care in NICUs Nationwide

Prolacta Bioscience is the first and only company to offer hospitals a complete line of 100% human milk-based neonatal nutritional products to meet the nutritional needs of the most fragile infants in the neonatal intensive care unit (NICU). When used as part of an exclusive human milk diet (EHMD),<sup>1</sup> Prolacta's neonatal nutritional products are clinically proven to improve health outcomes<sup>2,3,4</sup> and reduce hospital costs<sup>5,6</sup> for critically ill, extremely premature infants weighing between 500 and 1250 g (1 lb 2 oz to 2 lb 12 oz) at birth, as compared to cow milk-based fortifier or cow milk-based preterm formula.

*Prolacta's neonatal nutritional products are intended for hospital use as directed by a physician.*

## Nutritional & Caloric Human Milk Fortifiers

- **Prolact+ H<sup>2</sup>MF**<sup>®</sup> human milk fortifier, introduced to hospitals in 2006, remains the world's first and only human milk fortifier made with 100% human milk instead of cow milk. When added to mother's own milk or donor breast milk, Prolact+ H<sup>2</sup>MF provides extra calories, protein and minerals to help meet the nutritional needs of extremely preterm infants. It is available in +4, 6, 8 and 10 Cal/fl oz and is ordered by a neonatologist based on the number of calories desired per feeding. Prolact+ H<sup>2</sup>MF may also be combined with Prolact CR<sup>®</sup> 100% human milk-based caloric fortifier to provide preemies with added human milk fat. Depending on the calorie concentration, it takes approximately eight bottles of donor breast milk to make one bottle of Prolact+ H<sup>2</sup>MF.

EDITORIAL NOTE: The term "human milk fortifier" (HMF) is a generic product name for a nutritional supplement (made from either cow milk or human milk) that is added to mother's own milk or donor breast milk to meet the dietary needs of premature babies in the NICU. This generic term can cause confusion for parents and hospital staff alike. Some mistakenly assume that "human milk fortifier" may imply that the product is made from human milk, which is not the case. There is only one human milk-based HMF available today: Prolact+ . "H<sup>2</sup>" stands for (human) human milk fortifier. It remains the first and only HMF made exclusively from 100% human milk. All other products labeled "human milk fortifier" are made from cow milk.

- **Prolact CR**<sup>®</sup> is the first and only human milk caloric fortifier. It is a pasteurized formulation of human milk fat and permeate derived from donor milk that increases the caloric content of infant feedings by 2.5 Cal/mL. On average, Prolact CR is composed of 25% milk fat and is used with either mother's own milk or donor milk as a natural way to give preemies the added calories they require.

## Premature Infant Formula

When mother's own milk is unavailable, Prolacta offers a fortified "ready-to-feed" premature infant formula made from 100% human milk, instead of cow milk, that provides an easy and convenient way to provide an EHMD.

- **Prolact RTF** is the first and only human milk-based premature infant formula. It delivers standardized caloric content of 24, 26, or 28 Cal/fl oz.

## Donor Human Milk

- **Prolact HM**<sup>®</sup> introduced the first protein- and calorie-standardized donor human milk product to hospitals. When mother's own milk is unavailable, Prolact HM is formulated to deliver a standardized minimum of 20 Cal/fl oz and an average of 1.1 g of protein per 100 mL, so neonatologists can ensure that the nutritional content of each feeding meets the nutritional needs of extremely preterm infants in the NICU. Prolact HM is only used when mothers are unable to provide breast milk.
- **PremieLact**<sup>®</sup> was the first human milk nutritional product for trophic feeds. When mother's own milk is unavailable, this product may be used as a trophic feed to "prime the gut" for larger enteral feeds without wasting large amounts of donor milk.

EDITORIAL NOTE: Appropriate nutrition is critical to micropreemies' survival. Prolacta pools large quantities of donated milk to ensure a minimum of 20 Cal/fl oz and an average of 1.1 g of protein per 100 mL in Prolact HM.

## Understanding an Exclusive Human Milk Diet

An EHMD is associated with lower mortality and morbidity in extremely premature infants weighing between 500 and 1250 g (2 lb 12 oz) at birth without compromising growth.<sup>4,7</sup> This has led a growing number of hospitals to establish an EHMD protocol for these preemies, as opposed to cow milk-based nutrition or formula. In the NICU, an EHMD protocol typically comprises:

- Mother's own milk (best for baby) or donor milk
- Prolact+ H<sup>2</sup>MF fortifier, which is a 100% human milk-based nutritional fortifier made from human donor milk
- Prolact CR, a caloric fortifier made from 100% human milk that may also be added to mother's own milk or non-Prolacta donor milk to achieve the 20 Cal/fl oz baseline nutrition

### OR

- In lieu of the above combination, when mother's milk is not available, Prolact RTF 100% human milk-based premature infant formula is ordered in the NICU as primary nutrition in a calorie concentration of 24, 26, or 28 Cal/fl oz.

## Leading Provider of Human Milk-Based Nutritional Products to Hospital NICUs

Prolacta plays a vital role in helping hospitals meet the American Academy of Pediatrics (AAP) recommendation for the use of human milk for all preterm infants, whether mother's own milk or pasteurized donor human milk, if mother's milk is unavailable. For preemies weighing less than 1500 g (3 lb 4 oz), the AAP recommends fortifying breast milk with protein, minerals and vitamins to ensure optimal nutrient intake.<sup>8</sup>

- Hospitals choose Prolacta's 100% human milk-based neonatal nutritional products for the assurance that they are receiving safe, standardized donor milk formulations processed in a pharmaceutical-grade facility, under the strictest quality and safety guidelines, to protect the health and well-being of their most fragile patients.
- Prolacta leads the industry in the safety of neonatal nutritional products made from human breast milk. Prolacta stands alone in setting the standard for donor milk processing, pasteurization and product formulation with unsurpassed quality and safety measures. By Advancing the Science of Human Milk<sup>®</sup>, Prolacta is changing the standard of care in NICUs nationwide.

### References

1. An exclusive human milk diet (EHMD) is achieved when 100 percent of the protein, fat and carbohydrates in an infant's diet are derived from human milk. This diet includes a human milk-based human milk fortifier.
2. Sullivan S, Schanler RJ, Kim JH, et al. An exclusively human milk-based diet is associated with a lower rate of necrotizing enterocolitis than a diet of human milk and bovine milk-based products. *J Pediatr.* 2010;156(4):562-567. doi:10.1016/j.jpeds.2009.10.040. The randomized study of 207 infants weighing 500 to 1250 g compared the benefits of an exclusive human milk diet to a diet of both human milk-based and cow milk-based products.
3. Cristofalo EA, Schanler RJ, Blanco CL, et al. Randomized trial of exclusive human milk versus preterm formula diets in extremely premature infants. *J Pediatr.* 2013;163(6):1592-1595. doi:10.1016/j.jpeds.2013.07.011. The multicenter randomized controlled study examined 53 extremely premature infants weighing 500 to 1250 g who were fed either a bovine milk-based preterm formula or an exclusive human milk diet, comparing the duration of parenteral nutrition, growth and morbidity.
4. Abrams SA, Schanler RJ, Lee ML, Rechtman DJ. Greater mortality and morbidity in extremely preterm infants fed a diet containing cow milk protein products. *Breastfeed Med.* 2014;9(6):281-285. doi:10.1089/bfm.2014.0024. This cohort study included 260 extremely preterm infants born weighing less than 1250 g who received a diet that ranged from 100% cow milk to 100% human milk.
5. Ganapathy V, Hay JW, Kim JH. Costs of necrotizing enterocolitis and cost-effectiveness of exclusively human milk-based products in feeding extremely premature infants. *Breastfeed Med.* 2012;7(1):29-37. doi:10.1089/bfm.2011.0002. This cost-effectiveness analysis of 2,560 extremely premature infants less than 28 weeks' gestational age in 257 hospitals nationwide compared the impact of an exclusive human milk diet composed of mother's milk fortified with a human milk-based fortifier versus a diet composed of mother's milk fortified with cow milk-based fortifier.
6. Assad M, Elliott MJ, Abraham JH. Decreased cost and improved feeding tolerance in VLBW infants fed an exclusive human milk diet. *J Perinatol.* 2016;36(3):216-220. doi:10.1038/jp.2015.168. The study retrospectively looked at 293 preterm infants between gestational ages of 23 and 34 weeks and birth weights between 490 and 1700 g in the Level III NICU. The study compared the clinical and financial impacts between infants that were fed an exclusive human milk diet; cow milk-based fortifier and maternal milk; a mixed combination of maternal milk, cow milk-based fortifier and cow milk-based formula; or formula between March 2009 and March 2014.
7. Hair AB, Peluso AM, Hawthorne KM, et al. Beyond necrotizing enterocolitis prevention: improving outcomes with an exclusive human milk-based diet. *Breastfeed Med.* 2016;11(2):70-74. doi:10.1089/bfm.2015.0134. The multicenter retrospective study looked at 1,587 infants weighing less than 1250 g at birth who received a cow milk-based diet of mother's own milk fortified with cow milk-based fortifier and/or preterm formula compared to infants who received a human milk-based feeding protocol.
8. American Academy of Pediatrics. Breastfeeding and the use of human milk. *Pediatrics.* 2012;129(3):827-841. doi:10.1542/peds.2011-3552.

Note: Used the calculator from <http://www.matthewb.id.au/converter/grams-to-pounds-and-ounces-converter.html> to calculate and convert grams to pounds.