

# 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 in the NICU weighing between 500-1,250g (1 lb 1 oz to 2 lbs 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 and are available by prescription only.*

## Nutritional & Caloric Human Milk Fortifiers

- **Prolact+ H<sup>2</sup>MF**® 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 mom's 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 prescribed 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® 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 term for a nutritional supplement (made from either cow milk or human milk) that is added to mom's or donor breast milk to meet a preemie's dietary needs. This generic term can cause confusion for parents and hospital staff alike. Many mistakenly assume that because the product is labeled, "Human Milk Fortifier," it must be made from human milk, which is not the case. There is only one human milk-based HMF available today: Prolact+ H<sup>2</sup>MF – The 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**® 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 percent milk fat and is used with either mother's own or donor milk as a natural way to give preemies the added calories they require.

## Premature Infant Formula

When mom's or donor 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**® is the first and only protein- and calorie-standardized Donor Human Milk product. 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 1.1g of protein per 100 mL, so neonatologists can ensure 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.

EDITORIAL NOTE: Prolacta Bioscience is the only company to offer hospitals donor milk that is standardized for calories and protein. Calories are critical to micro preemies whose nutritional needs are vital to their survival. Only Prolacta, at its large-scale human milk processing facility, is able to pool large enough quantities of donor milk, and through its proprietary process, ensure a minimum of 20 Cal/fl oz and an average of 1.1g of protein per 100 mL.

- **Premielact®** is the first and only Human Milk 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.

### Understanding an Exclusive Human Milk Diet (EHMD)

An EHMD has been demonstrated to result in lower mortality and morbidity in premature infants weighing less than 1,250g (2 lbs 12 oz) at birth.<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 of:

- o Mother's own milk (best for baby) or donor milk
- o Prolact+ H<sup>2</sup>MF fortifier, which is a 100% human milk-based "nutritional fortifier" made from human donor milk
- o 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

- o In lieu of the above combination, when mother's milk is not available, Prolact RTF, 100% human milk-based premature infant formula, is prescribed 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 human donor milk, if mother's milk is unavailable. For preemies weighing less than 1,500g (3 lbs 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®, Prolacta is changing the standard of care in NICUs nationwide.

### References

1. An EHMD is when 100% of the protein, fat and carbohydrates in an infant's intake are derived solely from human milk.
2. Sullivan S, 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." *The Journal of Pediatrics*. April 2010. 156(4):562-567. doi: 10.1016/j.jpeds.2009.10.040. The randomized study of 207 infants weighing 500-1,250g compared the benefits of an exclusive human milk diet with a diet of both human milk-based and cow milk-based products.
3. Cristofalo EA, et al. "Randomized Trial of Exclusive Human Milk versus Preterm Formula Diets in Extremely Premature Infants." *The Journal of Pediatrics*. December 2013. 163(6):1592-1595. doi: 10.1016/j.jpeds.2013.07.011. The multicenter randomized controlled study examined 53 extremely premature infants weighing 500-1250g 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, et al. "Greater Mortality and Morbidity in Extremely Preterm Infants Fed a Diet Containing Cow Milk Protein Products." *Breastfeeding Medicine*. June 2014. 9(6): 281-0285. doi:10.1089/bfm.2014.0024. This cohort study included 260 extremely preterm infants born weighing less than 1,250g who received a diet that ranged from 100% cow milk to 100% human milk.
5. Ganapathy V, et al. "Costs of Necrotizing Enterocolitis and Cost-Effectiveness of Exclusively Human Milk-Based Products in Feeding Extremely Premature Infants." *Breastfeeding Medicine*. February 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, comparing the impact of an exclusive human milk diet composed of mother's milk fortified with a human milk-based fortifier versus mother's milk fortified with cow milk-based fortifier.
6. Assad M, et al. "Decreased Cost and Improved Feeding Tolerance in VLBW Infants Fed an Exclusive Human Milk Diet." *Journal of Perinatology*. March 2016. 36:216-220. doi: 10.1038/jp.2015.168. The study retrospectively looked at 293 preterm infants between gestational ages of 23 to 34 weeks and birth weights between 490-1,700g 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; mixed combination of maternal milk, cow milk-based fortifier and cow milk-based formula; and formula between March 2009 and March 2014.
7. Hair A, et al. "Beyond Necrotizing Enterocolitis Prevention: Improving Outcomes with an Exclusive Human Milk-Based Diet." *Breastfeeding Medicine*. March 2016. 11(2): 70-74. doi:10.1089/bfm.2015.0134. The study included more than 1,500 infants weighing less than 1,250g at birth from four large centers in TX, IL, FL and Calif. Researchers compared data from approximately two years before and two years after the implementation of an exclusive human milk diet in the study centers' neonatal intensive care units. Infants who received a diet of mother's milk fortified with a cow milk-based fortifier and/or preterm formula, were compared to infants who received an exclusive human milk diet, including mother's own or donor milk fortified with a Prolact+ H<sup>2</sup>MF®.
8. American Academy of Pediatrics. "Breastfeeding and the Use of Human Milk." February 2012. *Pediatrics*. 129(3): 827-841. doi:10.1542/peds.2011-3552. NOTE: Used calculator from <http://www.matthewb.id.au/converter/grams-to-pounds-and-ounces-converter.html> to calculate and convert grams to pounds.