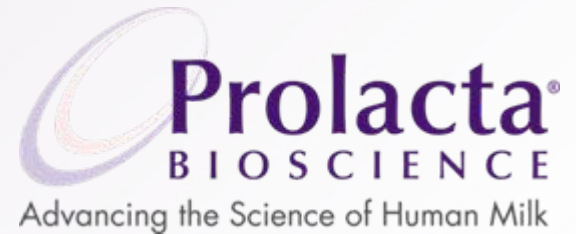


Using Donor Human Milk in Extremely Premature Infants



Introduction



- Scott Eaker, Vice President of Quality and Regulatory Affairs
- Scott Elster, Chief Executive Officer
- David Rechtman, MD, Chief Medical Officer

Agenda

- About Prolacta
- Our Babies
- Our Products
- Prolacta Research
- Four Pillars of Safety
- Human Milk Regulation

About Prolacta



- Prolacta Bioscience is a life science company dedicated to Advancing the Science of Human Milk®
- Our mission is to make a meaningful difference in the lives of thousands of the most vulnerable infants through world class research and innovative products.
- Prolacta offers a suite of specialty formulations of human milk to meet the nutritional needs of premature infants born weighing less than 1250 g.

Our Babies: Tyler – BW 950g



Product Overview

Human Milk Fortifier Prolact+ H²MF

The first and only 100% human milk-based fortifier for premature infants



Product Overview

Standardized Human Milk Products Neo20

Ready to feed when mom's milk or other donor milk is unavailable



Three fill volumes allow for appropriate mixing ratios with Prolact+ H²MF

Prolacta Research



Research is critical component of safety

•In vitro

- Viral reduction studies of pasteurization
- Fat, Ca, P loss during continuous feedings of Fortified Human Milk
- Osmolality of mixed feeding solutions
- Shelf-life studies

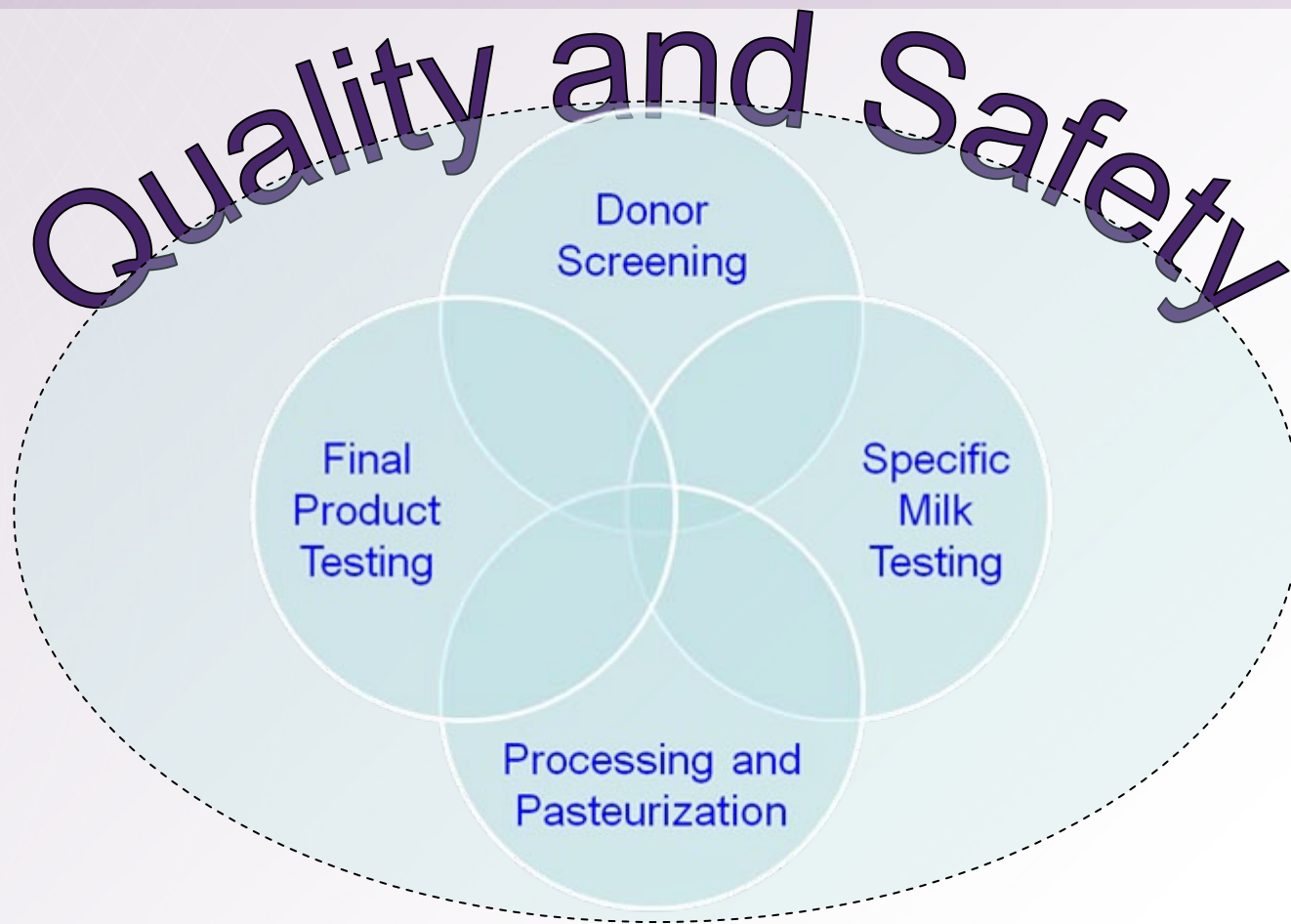
•Human clinical research - completed

- Ca absorption in premature infants fed an exclusive human milk diet (n = 15)
- Sheridan cohort study 66 patient open label study
- 207 patient study comparing completely human diet to standard of care - published
- 53 patient study comparing completely human diet with a formula diet

•Human Clinical research - in progress

- Prolacta diet in babies with congenital anomalies of the gut (15 of 30 enrolled)
- Case series investigating electrolytes in premature infants receiving Prolacta (23 infants completed scheduled to run until August 2011)
- Impact of human oligosaccharides, pre- and probiotics on stool flora in VLBW infants (30 of 36)

The Four Pillars of Safety



Donor Screening

- Before milk is collected by Prolacta, donors undergo a rigorous qualification process
 - Donor completes a health/lifestyle interview
 - Based on blood/plasma/tissue banking requirements
 - Non-standard responses reviewed by Medical Director
 - Donor approval from primary care physician
 - Pediatrician certification of infant's health
 - Donor confirms storage conditions of their milk
 - Blood draw for infectious disease testing (HIV-1, HIV-2, HTLV I, HTLV II, HBV, HCV and syphilis)
 - Donor submits a cheek swab to create a Donor DNA ID

Specific Milk Testing



- After milk is received by Prolacta, it undergoes direct safety testing
 - Each donation is pooled individually and tested for:
 - Drugs of abuse (amphetamines, marijuana, opiates, methamphetamines, benzodiazepine, cocaine, and primary metabolites)
 - Milk DNA ID – must match Donor DNA ID
 - *Bacillus cereus*
 - Only milk that passes all testing can be pooled for production

Processing and Pasteurization



- Prolacta's manufacturing process is designed to ensure a safe product
 - All processing occurs in certified cleanrooms that are regularly monitored for pathogens
 - All manufacturing employees have experience working with biologic products
 - Manufacturing and quality systems are designed to be compliant with pharmaceutical GMPs
 - Processing produces a standardized product to ensure consistency in feeding

Processing and Pasteurization

- Highly controlled pasteurization process
 - Vat pasteurization with jacketed temperature control
 - Multiple points of temperature monitoring
 - Validation of viral inactivation
 - Studies performed in-vitro using model virus
 - >5.8 to >7.7 log reduction of lipid enveloped viruses (HIV, HBV, HCV)
 - >2.6 log reduction of non-lipid enveloped virus (HAV)

Final Product Testing

- Samples are taken from each lot of product to test for:
 - Viral contamination – HIV, HBV, HCV by highly sensitive PCR methods
 - Microbial contamination – Total aerobic count, *B. cereus*, coliform and *E. coli*, *P. aeruginosa*, *S. aureus*, *Salmonella*, yeast and mold
 - Nutritional Panel – protein, fat, calories, minerals
 - These exact results are used to create lot-specific labeling

Exempt Infant Formula Labeling



- Prolacta labels its fortifiers in compliance with the requirements of the Infant Formula Act

Prolact+4 H²MF[®] Human Milk Fortifier (Human, Pasteurized)		20mL
CAUTION: Nutritionally incomplete. *Additional vitamins and iron may be required. To be used only under the supervision of a physician.		Must be mixed with 80 mL human milk
Nutrients per 20 mL (1 Bottle)		Minerals
Protein 1.2 g	Carbohydrate 1.8 g	Calcium 103.0 mg
Fat 1.8 g	Calories 29.4	Manganese ..<12.0 mcg
Vitamins*		Phosphorus..53.8 mg
Vitamin A ..61.2 IU	Vitamin B ₆ 4.1 mcg	Copper 63.4 mcg
Vitamin D ..26.0 IU	Vitamin B ₁₂ <0.1 mcg	Magnesium ... 4.7 mg
Vitamin E ... 0.4 IU	Niacin 52.4 mcg	Sodium 37.4 mg
Vitamin K ..<0.2 mcg	Folate 5.4 mcg	Iron 0.1 mg
Thiamine	Pantothenic	Potassium 25.0 mg
(Vit. B ₁) 4.0 mcg	Acid 74.8 mcg	Zinc 0.7 mg
Riboflavin	Vitamin C	Chloride 28.6 mg
(Vit. B ₂) ... 15.0 mcg	(Ascorbic Acid) ..<0.2 mg	
		Ingredients: Human Milk, contains less than 2% of the following: calcium glycerophosphate, calcium gluconate, sodium citrate, calcium chloride, potassium citrate, magnesium phosphate, calcium carbonate, zinc sulfate, cupric sulfate

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Intended for Premature/ LBW Infants Fed Human Milk

Directions for Preparation and Use:
Store at -20°C or colder until ready to use. Do not microwave. Once thawing process begins, administer within 48 hours. Mix full bottle with 80 mL of human milk. Gently swirl bottle to mix; DO NOT SHAKE. Once mixed, keep refrigerated until used. The health of the infant depends on carefully following the directions for preparation and use.


Product Code: 93901-20

LOT: MPP4-999999-X

USE BY: MMM DD, YYYY

Food Labeling

- Prolacta's Neo20 is labeled in compliance with the Nutritional Labeling and Education Act



Neo20™

Human Milk (Human, Pasteurized)

50mL

<h3 style="margin: 0;">Nutrition Facts</h3> <p style="margin: 0;">Serving Size 50mL Servings 1</p> <p style="margin: 0;">Calories 35.1</p> <p style="margin: 0;">*Percent daily values (DV) have not been formally set for LBW and VLBW infants; actual values are given</p>	<table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="border-bottom: 1px solid black;">Amount/serving</th> <th style="border-bottom: 1px solid black;">%DV*</th> </tr> </thead> <tbody> <tr> <td>Total Fat</td> <td>2.0 g*</td> </tr> <tr> <td>Sodium</td> <td>8.2 mg*</td> </tr> <tr> <td>Potassium</td> <td>21.6 mg*</td> </tr> <tr> <td>Vitamin A</td> <td>98.2 IU*</td> </tr> <tr> <td>Calcium</td> <td>16.0 mg*</td> </tr> <tr> <td>Phosphorus</td> <td>7.5 mg*</td> </tr> <tr> <td>Zinc</td> <td><0.1 mg*</td> </tr> <tr> <td>Chloride</td> <td><25.0 mg*</td> </tr> </tbody> </table>	Amount/serving	%DV*	Total Fat	2.0 g*	Sodium	8.2 mg*	Potassium	21.6 mg*	Vitamin A	98.2 IU*	Calcium	16.0 mg*	Phosphorus	7.5 mg*	Zinc	<0.1 mg*	Chloride	<25.0 mg*	<table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="border-bottom: 1px solid black;">Amount/serving</th> <th style="border-bottom: 1px solid black;">%DV*</th> </tr> </thead> <tbody> <tr> <td>Total Carb</td> <td>3.6 g*</td> </tr> <tr> <td>Sugars</td> <td>2.9 g*</td> </tr> <tr> <td>Protein</td> <td>0.6 g*</td> </tr> <tr> <td>Vitamin C</td> <td><0.5 mg*</td> </tr> <tr> <td>Iron</td> <td><0.1 mg*</td> </tr> <tr> <td>Magnesium</td> <td>2.1 mg*</td> </tr> <tr> <td>Copper</td> <td>36.1 mcg*</td> </tr> <tr> <td>Manganese</td> <td><61.1 mcg*</td> </tr> </tbody> </table>	Amount/serving	%DV*	Total Carb	3.6 g*	Sugars	2.9 g*	Protein	0.6 g*	Vitamin C	<0.5 mg*	Iron	<0.1 mg*	Magnesium	2.1 mg*	Copper	36.1 mcg*	Manganese	<61.1 mcg*
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Ingredients: Human Milk

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Product Code: 92001-50N



LOT: MN20-999999-X USE BY: MMM DD, YYYY

Regulatory Environment



- The regulatory environment for human milk products is complex
 - Infant formula regulations
 - Food regulations
 - Voluntary standards and recommendations (CDC, ADA, HMBANA)
 - State tissue banking regulations

Regulatory Environment

- Each state's tissue banking regulations have slightly different requirements
 - Required blood tests for donors
 - Medical director licensing requirements
 - Record keeping requirements
- Differences in regulations present an impediment to breakthrough improvements in safety
- A single standard incorporating all requirements would improve confidence and acceptance of human milk in NICU

Questions