KLAIRE LABS®

TECHNICAL DATA SHEET

Target b²™

- *Lactobacillus fermentum* CECT5716 (Hereditum® Lc40)
- Probiotic formula demonstrated to support breast health during lactation and immune health in infants†

Introduction

Exclusive breastfeeding is recommended by the World Health Organization for infants up to at least 6 months of age.[1] Breast milk provides all the nutrients and components necessary for proper infant development and growth. Moreover, breastfeeding also appears to have important effects on the infant microbiome that can be determinative of later health. Unfortunately, during the first weeks of breastfeeding, women often experience a range of discomforts and breast health issues that can interfere with lactation and nursing.

Breast milk is one of the primary contributors to the development of gut microbiota of the infant. Enteric-breast circulation occurs and is higher in late pregnancy and lactation. This may explain why orally administered probiotic supplements can directly influence health of breast microbiota.[2] Although the study of probiotics in human milk is a relatively recent field of research, the existence of a human milk microbiome has been described for more than a decade.

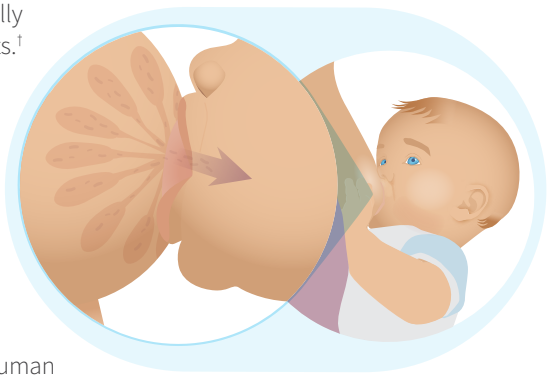
Current research is focused on bacterial composition of the breast milk microbiome, as well as on how the maternal environment and mode of delivery influence it. Under healthy conditions, breast milk has been shown to contain Lactobacilli, Streptococci, Staphylococci, *Enterococcus* spp, and Bifidobacteria, as the predominant bacterial groups.[3] Although they may alter bacterial load, conventional drug treatment options fall short when it comes to relieving breastfeeding discomforts, and have well-documented negative impact on the maternal and infant microbiota.[4]

Infant benefits of nursing

- Complete nutrition
- Immune development
- Microbiota development
- Mother-child bonding

Research has shown that Lactobacilli isolated from breast milk demonstrate significant immunomodulatory properties.†[5] Recent studies further demonstrate that breast comfort, infant immune health, and the balance of bacteria in the breast and gut microbiota can be favorably influenced by supplementation with probiotics. Target b² is a novel probiotic formula containing *Lactobacillus fermentum* CECT5716 (Hereditum Lc40), a unique strain clinically shown to improve breast comfort in breastfeeding women and immune health in infants.†

THE ENTERO-MAMMARY PATHWAY



Product features

- Clinically shown to support infant immune health†
- Clinically demonstrated to provide a safe and effective approach to preventing, reducing, and resolving lactation discomforts and dysbiosis†

Target b² clinical research

L. fermentum CECT5716 (Hereditum Lc40) has been shown to provide a safe and effective approach to maximizing breastfeeding comfort and duration while supporting infant immune health. Many clinical trials have validated the efficacy of *L. fermentum* in human health. Two clinical trials to date have specifically demonstrated its effects on breast health.

In an open-label, 3-arm study comparing two strains of Lactobacilli and conventional treatment in 352 women with lactation-related discomfort and mammary dysbiosis,[6] *L. fermentum* CECT5716 (Hereditum Lc40) and another, commercially unavailable, *Lactobacillus* strain were administered at 9 billion CFU per day for 21 days. A third (control) group received conventional treatment. On day 0, the mean bacterial counts in milk samples of the three groups were similar, and Lactobacilli could not be detected. On day 21, mean bacterial counts in the probiotic groups were significantly improved compared with the control group. Women taking probiotics showed more improvements in comfort and had less recurrence compared to the conventional method. The authors concluded that *L. fermentum* CECT5716 represented an efficient alternative for supporting breast comfort and healthy microbiota during breastfeeding.†

†These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

In the second study—a randomized, double-blind, placebo-controlled clinical trial—researchers in Spain evaluated three different amounts of *L. fermentum* CECT5716 to assess its ability to favorably alter microbial balance in the breast milk of 148 women suffering from breastfeeding discomfort.[7] Three groups received the probiotic strain for three weeks, at 3, 6, or 9 billion CFU per day. A fourth group (controls) received maltodextrin. The primary outcome of the study was bacterial counts in breast milk. Secondary outcomes included IgA and IL-8 concentrations in breast milk, and also scores related to breast pain. After three weeks, bacterial balance and breastfeeding was significantly improved in the probiotic groups compared to baseline levels, whereas there was no change in the maltodextrin group.

Target b^2 with Hereditum Lc40[6]

Intervention	Complete Resolution	Recurrence (90 days)
Hereditum Lc40	88%	10.5%
Conventional Therapy	29%	30.7%

Other research has demonstrated that *L. fermentum* CECT5716 supports immune health and is safe and well tolerated in both adults and infants.[8-11]

Conclusion

Conventional therapies for lactation discomfort are ineffective and carry many disadvantages, including side effects, maternal dysbiosis, loss of maternal-infant bonding, and undesirable effects on infant immune system maturation. The advent of safe, effective support options for maternal breast and infant immune health should be a matter of intense interest for obstetricians, lactation consultants, nurses, midwives, and other allied health professionals who provide primary care for breastfeeding mothers.

Formula

SUGGESTED USE: 1 capsule, 1 to 3 times daily (3 to 9 billion CFU) or as directed by a healthcare professional.

Supplement Facts

Serving Size 1 capsule

Amount Per Capsule		% Daily Value
Lactobacillus fermentum 3 billion CFU CECT5716 (Hereditum®‡ Lc40)	30 mg	*

*Daily Value not established.

NON GMO

Other ingredients: Microcrystalline cellulose, silicon dioxide, vegetarian capsule (hydroxypropyl methylcellulose, water), maltodextrin, sucrose, calcium carbonate, and sodium ascorbate.

‡Hereditum® is a registered trademark of Biosearch, S.A., Spain.

CONTAINS MILK.

TB2 90 capsules

How supplied

3B CFU per capsule.

Storage

May be stored at room temperature or in refrigerator until expiration date. Close lid tightly to minimize exposure to moisture.

References

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