

2018 Edition

# CLINICAL GUIDE TO PROBIOTIC PRODUCTS AVAILABLE IN CANADA

Indications, Dosage Formats, and Clinical Evidence to Date

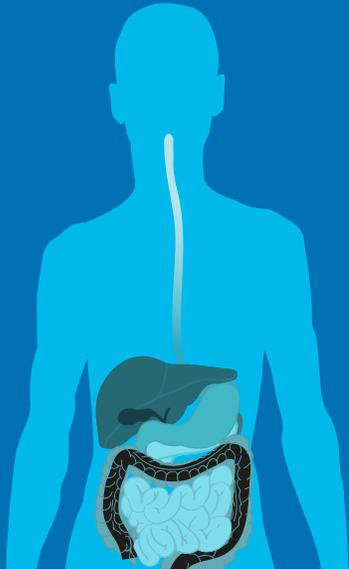
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## **WHAT is this:**

A Practice Tool to Assist with Clinical Decision Making for Appropriate Probiotic Therapy for Your Patients

## **WHO is the intended user?**

This Clinical Guide is designed to translate scientific evidence available for probiotic products to practical, clinically relevant information. It is intended to be used as clinical decision-making tool, enabling clinicians to easily select the appropriate product, dose, and formulation for a specific indication.

## **WHY is this needed?**

Currently, the body of evidence for probiotic interventions is growing along with popular demand for these products. There is evidence to support the use of probiotic products for a variety of indications beyond gut health, however applications and results are strain-specific.

Due to frequent changes in commercial availability of probiotic strains, new published evidence and growing research, an annual review and updates of this Clinical Guide has been conducted since 2008. A general lack of adverse effects attributable to probiotics supports the wide use of these products, but ongoing investigation is recommended.

## **HOW is this tool reviewed?**

A systematic literature review using pre-defined inclusion criteria was undertaken to identify studies of defined clinical outcomes for specific probiotic strain(s). Commercially available products containing said strain(s) were identified, and the levels of evidence were used to rate the strength of expected benefit. This information was compiled into a chart format. Data was assessed by a group of independent expert reviewers.

In the case of probiotics, the clinical evidence must be linked to specific formulations (as defined by genus, species, alphanumeric designation or strain, number of live bacteria present, the blend of probiotic strains present and finally, non-active ingredients present).

Every attempt was made by the author and reviewers to include the published clinical data for the available probiotic formulations. To avoid selection bias toward any specific formulation, we have conducted a literature search of two databases (PubMed, EMBASE) and contacted our independent experts to identify any published or unpublished studies.

Our aim is to ensure that the appropriate product/strain is selected for the desired outcome. This Clinical Guide is not meant to be interpreted as systematic review, or a “clinical practice guideline”, nor is it an endorsement for companies to market health claims.

Readers are strongly encouraged to review the evidence listed for each product for themselves. Please refer to individual publications for specifics of patient populations studied (e.g. age, gender, comorbidities) and details of clinical effect (statistical significance, size of treatment effect, precision of the confidence intervals).

## WHY are only limited number of products included?

All of the Inclusion criteria listed below must be satisfied for a product to be listed in the clinical guide:

1. Commercially available in Canada (or USA) as a supplement or probiotic-containing food.
2. Generally Recognized as Safe status (FDA) and/or Natural Product Number (Health Canada) for probiotic strain(s) used in the products.
3. Favourable published clinical evidence for the particular strain(s) present in each product.
4. For products containing multiple strains, evidence must be for the specified combination and NOT extrapolated from the evidence for the separate probiotic strains.

### Note:

Some products are excluded from the current edition due to changes in strains used.

### Clinical Pearl:

Indications for use are based on specific strains or combinations studied together.

### Caution:

Extrapolation of current data and recommendations to be applied for different combinations of probiotic strains is not permitted.

#### Disclaimer:

The statements made regarding products listed here have not been evaluated by the Food and Drug Administration or Health Canada (unless otherwise indicated). These products are not intended to diagnose, treat, cure or prevent any disease. Products, services, information and other content provided on this Site, including information that may be provided on this Site directly or by linking to third-party websites are provided for informational purposes only. Please consult with a physician or other healthcare professional regarding any medical or health related questions. Manufacturer indications for use can be found on product labels. This chart is reflective of published evidence available to date. It does not represent an endorsement of any specific product. Work on this guide is done independently and without financial conflict. In order to minimize bias, publishing and distribution efforts are coordinated via Alliance for Education in Probiotics (AEProbio). We are grateful for unrestricted publishing grant AEProbio is providing for continuous efforts to translate science into clinically applicable form.

2018 Version, valid until Dec. 31, 2018. © BHSofInc. Please forward any questions or comments to the author Dragana Skokovic-Sunjic ([dsunjic@bhssoftinc.com](mailto:dsunjic@bhssoftinc.com))

## Acronyms:

<b>AAD</b>	Antibiotic associated diarrhea - Prevention	<b>IBS</b>	Irritable bowel syndrome
<b>BV</b>	Bacterial vaginosis	<b>ID</b>	Infectious diarrhea
<b>C</b>	Constipation	<b>LH</b>	Liver Health (NASH/NAFLD/MHE; as adjunct to standard therapy; see studies for specific population)
<b>CDAD</b>	Clostridium difficile associated diarrhea - Prevention	<b>M/A</b>	Mood and Affect (symptoms related to stress/anxiety; not a substitute for standard treatment)
<b>CE/AD</b>	Childhood eczema/ Atopic dermatitis	<b>NEC*</b>	Necrotizing Enterocolitis (newborn) *as per hospital protocol, not for self-administration
<b>CID</b>	Common infectious disease - community acquired	<b>NI</b>	Nosocomial infections prevention - hospital acquired
<b>CMPA</b>	Cow Milk Protein Allergy	<b>OH</b>	Oral health (reductions of tonsillitis, laryngitis, and dental caries)
<b>Colic</b>	Colic	<b>Regurg/ GI Mot</b>	Reduces regurgitation/ Improves gastrointestinal motility
<b>FAP</b>	Functional abdominal pain	<b>TD</b>	Traveler's diarrhea prevention
<b>HP</b>	Helicobacter pylori - Adjunct to standard eradication therapy	<b>VC</b>	Vulvovaginal candidiasis
<b>IBD-P</b>	Inflammatory bowel disease - Pouchitis	<b>WM</b>	Weight Management (aids in reduction of body weight, body fat mass and waist circumference)
<b>IBD-UC</b>	Inflammatory bowel disease - Ulcerative colitis – Adjunct to standard therapy	<b>B</b>	Billion

## Levels of evidence:

<b>Level I</b>	Evidence obtained from at least one properly designed randomized trial. (HIGHEST LEVEL)
<b>Level II</b>	Evidence obtained from well-designed controlled trials without randomization /Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group/ Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled trials might also be regarded as this type of evidence
<b>Level III</b>	Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees

# Indications for Adult Health:

Brand Name	Probiotic Strain	Dosage Form	CFU/dose	No of doses/day	TD	C	HP	M/A	CID	AAD	CDAD	OH	ID	IBS	IBD-UC	WM	IBD-P	LH
<b>Align®</b>	<i>B. longum 35624</i>	Capsules	1B/capsule	1 capsule										I (1-4)				
<b>Align® Chewables</b>	<i>B. longum 35624</i>	Tablet	1B/Tablet	1 tablet										I (1-4)				
<b>Bio-K+® CL1285</b> *	<i>L. acidophilus CL 1285</i> <i>L. casei LBC80R</i> <i>L. rhamnosus CLR2</i>	Regular Capsule Strong Capsule "Travel Protection" Extra Strength Ferm. milk lq. Ferm. rice lq. Ferm. soy lq	12.5B/capsule 25B/capsule 30B/capsule 50B/capsule 50B/tub 50B/tub 50B/tub	1-2 capsules 1-2 capsules 1-2 capsules 1-2 capsules ½-1 tub ½-1 tub ½-1 tub						I (5-7)		I (6-9)						
<b>BioGaia® ProTectis® chew tabs</b>	<i>L. reuteri DSM 17938</i>	Chew. tabs	100M/tab	1 tab		I (16)		I (12-15)		II (11)			II (10)					
<b>BioGaia® ProTectis® drops</b>	<i>L. reuteri DSM 17938</i>	Drops	100M/5drops	5 drops		I (16)		I (12-15)		II (11)			II (10)					
<b>BioGaia® ProTectis® drops with Vitamin D</b>	<i>L. reuteri DSM 17938</i>	Drops	100M/5drops	5 drops		I (16)	I (12-15)			II (11)			II (10)					
<b>CalmBiotic™</b>	<i>Bifidobacterium longum R0175</i> <i>L. helveticus R0052</i>	Stick	3B CFU/stick	1 stick				II (17-19)										
<b>CulturedCare™ ProbioticGum</b>	<i>Streptococcus salivarius K12</i>	Lozenge	0.5B/lozenge	2-10 lozenges									II (43,44)					
<b>Culturelle®</b>	<i>L. rhamnosus GG</i>	Capsule	10B/capsule	1 capsule			I (21)			I (20)								

\* - Product requires refrigeration

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# Indications for Adult Health:

Brand Name	Probiotic Strain	Dosage Form	CFU/dose	No of doses/day	TD	C	HP	M/A	CID	AAD	CDAD	OH	ID	IBS	IBD-UC	WM	IBD-P	LH
<b>Digestive Care™ Daily Probiotic</b>	<i>L. plantarum 299v</i>	Capsule	10B/capsule	1-2 capsule						III (22)	III (23)			I (24-26)				
<b>Digestive Care™ Travel Probiotic</b>	<i>L. rhamnosus GG</i>	Capsule	10B/capsule	1 capsule			I (21)			I (20)								
<b>FlorastorMax®</b>	<i>Saccharomyces boulardii</i> <i>lyo CNCM I-745</i>	Sachet	10B/sachet	1 sachets	I (30-32)		I (34-36)			I (27,28)	I (8,9,28,29)				III (33)			
<b>Florastor®</b>	<i>Saccharomyces boulardii</i> <i>lyo CNCM I-745</i>	Capsule Sachet	5B/capsule 5B/sachet	1-2 capsules 1-2 sachets	I (30-32)		I (34-36)			I (27,28)	I (8,9,28,29)				III (33)			
<b>HMF by Genestra</b>	<i>L. acidophilus CUL60</i> <i>L. acidophilus CUL21</i> <i>B. bifidum CUL20</i> <i>B. lactis CUL34</i>	Capsule Forte Intensive Super Powder Intensive 50	2.5B/capsule 10B/capsule 25B/capsule 10B/1 scoop (1gram) 50B/capsule	1-2 capsule 1-2 capsule 1-2 capsule 1-2 scoops 1 capsule							II (37)			II (38)				
<b>Mutaflor® *</b>	<i>Echerichia coli Nissle 1917</i>	Capsule	2.5-25B/capsule	1-2 capsules											I (39-42)			
<b>PerioBalance™</b>	<i>L. reuteri ATCC 55730</i> <i>L. reuteri ATCC PTA 5289</i>	Lozenge	100M each/lozenge	2 lozenges									II (45,46)					
<b>Probiotic Sticks</b>	<i>Bifidobacterium longum</i> <i>R0175</i> <i>L. helveticus R0052</i>	Stick	3B CFU/stick	1 stick					II (17-19)									
<b>TuZen®</b>	<i>L. plantarum 299v</i>	Capsule	10B/capsule	1-2 capsules						III (22)	III (23)			I (24-26)				
<b>Ultra Probiotic Complex by GNC</b>	<i>L. acidophilus CUL60</i> <i>L. acidophilus CUL21</i> <i>B. bifidum CUL20</i> <i>B. lactis CUL34</i>	Packet Capsule	25B/packet 25B/ 50B/ 75B per capsule	1-2 packets 1-2 capsule							II (37)			II (38)				

\* - Product requires refrigeration

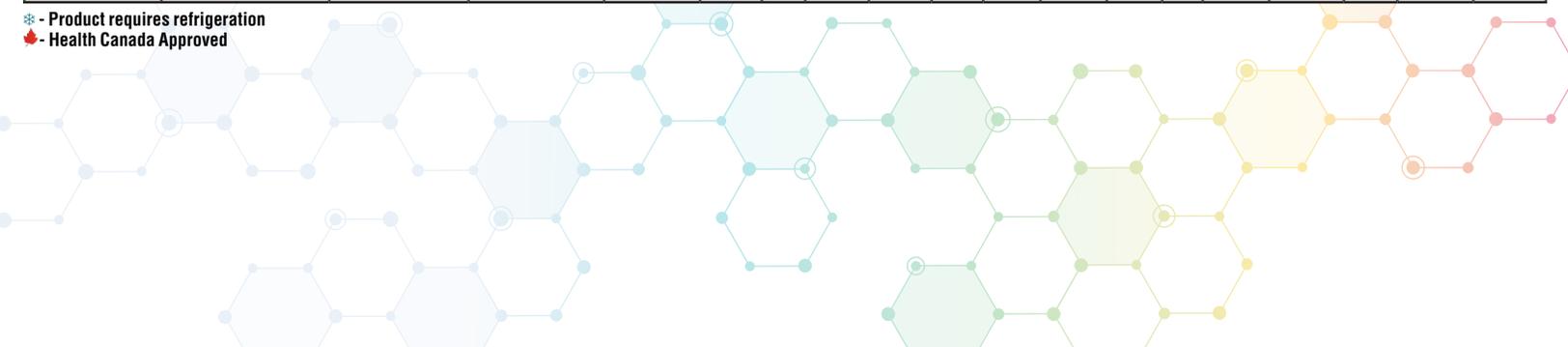
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# Indications for Adult Health:

Brand Name	Probiotic Strain	Dosage Form	CFU/dose	No of doses/day	TD	C	HP	M/A	CID	AAD	CDAD	OH	ID	IBS	IBD-UC	WM	IBD-P	LH
<b>UltraFlora® Control</b>	<i>B. animalis ssp. Lactis 420 (B420)</i>	Capsule	10B CFU/capsule	1 capsule												I  (47)		
<b>UltraFlora® Cold Support</b>	<i>L. plantarum HEAL9</i> <i>L. paracasei 8700:2</i>	Capsule	0.5B each per capsule	1 capsule					I  (48,49)									
<b>UltraFlora® Intensive Care</b>	<i>L. plantarum 299v</i>	Capsule	10B CFU/capsule	2 capsules						III (22)	III (23)			I  (24-26)				
<b>VSL#3®*</b>	<i>L. acidophilus SD5212</i> <i>L. casei SD5218</i> <i>L. bulgaricus SD5210</i> <i>L. plantarum SD5209</i> <i>B. longum SD5219</i> <i>B. infantis SD5220</i> <i>B. breve SD5206</i> <i>S. thermophilus SD5207</i>	Sachet	450B/sachet	1-4 sachets		II (50)									I  (51-53)		I  (52-56)	I (57-60)
<b>Visbiome™*</b>	<i>L. acidophilus SD5212</i> <i>L. casei SD5218</i> <i>L. bulgaricus SD5210</i> <i>L. plantarum SD5209</i> <i>B. longum SD5219</i> <i>B. infantis SD5220</i> <i>B. breve SD5206</i> <i>S. thermophilus SD5207</i>	Sachet	450B/sachet	1-4 sachets		II  (50)									I  (51-53)		I  (52-56)	I (57-60)

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# Indications for Pediatric Health:

Brand Name	Probiotic Strain	Dosage Form	CFU/dose	No of doses/day	Colic	C	HP	CID	CE/AD	AAD	CDAD	FAP	NEC*	OH	ID	IBS	IBD-UC	Regurg/GI Mot	NI	LH	
<b>BioGaia® ProTectis® Chew tabs</b>	<i>L. reuteri DSM 17938</i>	Chew. tabs	100M/tab	1 tab	I (65-66)	I  (75,76)		I (79,80)	II (81)	I (74)		I (77,78)			I  (69-73)	I (77,78)		I (61-63)			
<b>BioGaia® ProTectis® Drops</b>	<i>L. reuteri DSM 17938</i>	Drops	100M/5drops	5 drops	I  (65-66)	I  (75,76)		I (79,80)	II (81)	I (74)		I (77,78)	I (64)		I  (69-73)	I (77,78)		I (61-63)			
<b>BioGaia® ProTectis® Drops with Vitamin D</b>	<i>L. reuteri DSM 17938</i>	Drops	100M/5drops	5 drops	I (65-88)	I (75,76)		I (79,80)	II (81)	I (74)		I (77,78)	I (64)		I (69-73)	I (77,78)		I (61-63)			
<b>CulturedCare™ ProbioticGum</b>	<i>Streptococcus salivarius K12</i>	Lozenge	1B/lozenge	1-5 lozenges										II  (43,44)							
<b>Culturelle® Kids</b>	<i>L. rhamnosus GG</i>	Powder	5B/packet	2-4 packets					I (93-99)	I  (88,89)		I (90,91)			I  (82-,87)	I (90,91)			I (92)	II (100,101)	
<b>Digestive Care™ Kids Daily Probiotic</b>	<i>L. rhamnosus GG</i>	Powder	5B/packet	1-2 packets					I (93-99)	I (88,89)		I (90,91)			I (82-87)	I (90,91)				I (92)	II (100,101)
<b>FloraBABY™ ❄️</b>	<i>B. breve HA-129</i> <i>L. rhamnosus HA-111</i> <i>B. bifidum HA-132</i> <i>B. infantis HA-116</i> <i>B. longum HA-135</i>	Powder	4B/scoop	1 scoop									II (102)								
<b>Florastor® Kids</b>	<i>Saccharomyces boulardii lyo CNCM I-745</i>	Capsule Sachet	5B/capsule 5B/sachet	1-2 capsules 1-2 sachets			I (35,106)			I  (106)	III (107)				I (103-105)						
<b>HMF Fit for School by Genestra [50 mg vitamin C]</b>	<i>L. acidophilus CUL21</i> <i>L. acidophilus CUL60</i> <i>B. lactis CUL34</i> <i>B. bifidum CUL20</i>	Tablet	12.5B/tablet	1 tablet				I  (109)													

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# Indications for Pediatric Health:

Brand Name	Probiotic Strain	Dosage Form	CFU/dose	No of doses/day	Colic	C	HP	CID	CE/AD	AAD	COAD	FAP	NEC*	OH	ID	IBS	IBD-UC	Regurg/GI Mot	NI	LH
<b>innovite HEALTH® Kids Daily Probiotics</b>	<i>B. lactis</i> UABLA-12 <i>L. acidophilus</i> DDS®-1	Powder	5B/gram	2 grams				 (110)	I (111)											
<b>Nestlé® Good Start® Baby Probiotic Drops</b>	<i>B. lactis</i> BB-12	Drops	1B/6 drops	6 drops				I (112)	🇨🇦	I (113)										
<b>Probiotic Baby</b>	<i>B. lactis</i> BB-12	Drops	1B/6 drops	6 drops				I (112)		I (113)										
<b>UltraFlora® Baby</b>	<i>L. rhamnosus</i> GG <i>B. lactis</i> BB-12	Drops	1B/6 drops	6 drops				 (114)	🇨🇦											
<b>UltraFlora® Children's</b>	<i>L. acidophilus</i> NCFM® <i>B. animalis</i> subsp <i>lactis</i> BI-07	Chewable tablet	2.5B each/ chewable tablet	1-2 chew tablets				I (115)												
<b>VSL#3® ❄️</b>	<i>L. acidophilus</i> SD5212 <i>L. casei</i> SD5218 <i>L. bulgaricus</i> SD5210 <i>L. plantarum</i> SD5209 <i>B. longum</i> SD5219 <i>B. infantis</i> SD5220 <i>B. breve</i> SD5206 <i>S. thermophilus</i> SD5207	Sachet	450B/sachet	1-2 sachets											I (116)	I (119)	I (117,118)			I (120)
<b>Visbiome™ ❄️</b>	<i>L. acidophilus</i> SD5212 <i>L. casei</i> SD5218 <i>L. bulgaricus</i> SD5210 <i>L. plantarum</i> SD5209 <i>B. longum</i> SD5219 <i>B. infantis</i> SD5220 <i>B. breve</i> SD5206 <i>S. thermophilus</i> SD5207	Sachet	450B/sachet	1-2 sachets											I (116)	I (119)	I (117,118)			I (120)

❄️ - Product requires refrigeration

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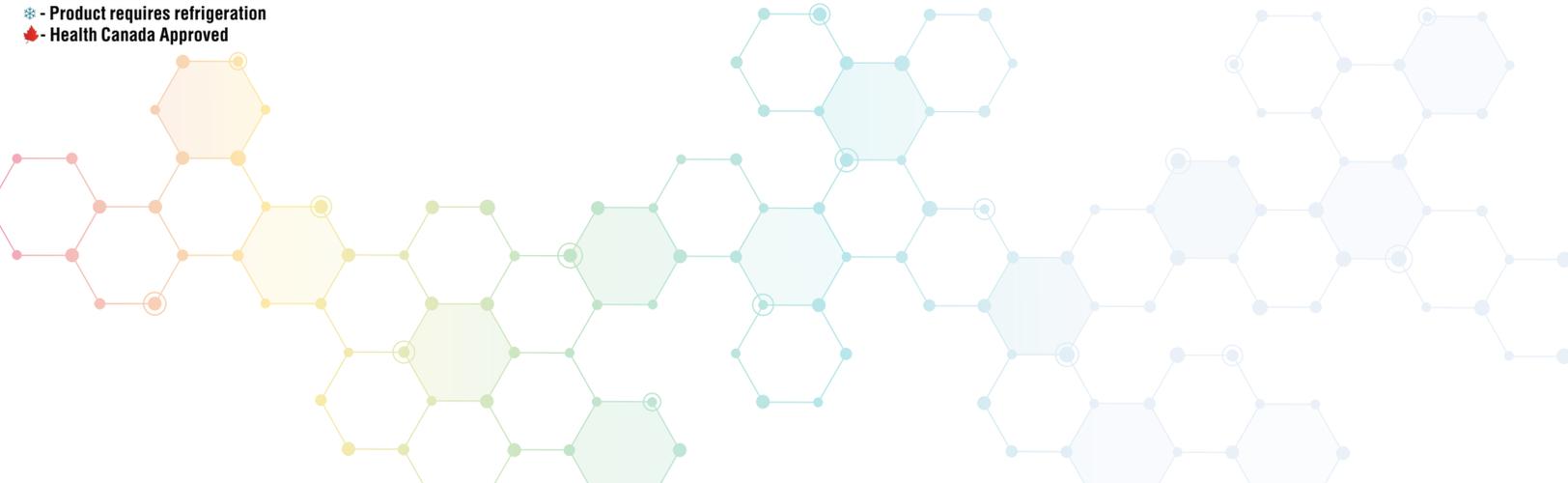
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# Indications for Vaginal Health:

Brand Name	Probiotic Strain	Dosage Form	CFU/dose	No of doses/day	BV	VC
<b>Fem-Dophilus®</b>	<i>L. rhamnosus GR-1</i> <i>L. reuteri RC-14</i>	Oral capsule	2.5B each/capsule	1 capsule	I (123-125)	I (121,122)
<b>ProB™ (RePhresh ProB)</b>	<i>L. rhamnosus GR-1</i> <i>L. reuteri RC-14</i>	Oral capsule	2.5B each/capsule	1 capsule	I (123-125)	I (121,122)
<b>Probiac BV®</b>	<i>L. acidophilus A-212</i> 0.4B <i>L. rhamnosus A-119</i> 6.8B <i>S. thermophilus A-336</i> 0.8B	Vaginal capsule	8B/capsule	1-2 capsules	II (126)	
<b>Provacare™</b>	<i>L. rhamnosus Lcr35</i>	Vaginal capsule	3.41B/capsule	2 capsules	I (128-130)	I (127)
<b>Purfem™</b>	<i>L. rhamnosus PBO1</i> <i>L. gasseri EN-153471 (EB01)</i>	Vaginal ovule	1B each/ovule	1 ovule	I (131,132)	
<b>UltraFlora™ Women's</b>	<i>L. reuteri RC-14</i> <i>L. rhamnosus GR-1</i>	Oral capsule	1B each/ capsule	2 capsules	I (134,135)	I (133)

❄ - Product requires refrigeration

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# Functional Foods with Added Probiotics:

Brand Name	Probiotic Strain	CFU/dose	No of doses/day	Children					Adult			
				ID	HP	AAD	CID	CMPA	AAD	IBS	C	CID
<b>Activia®*</b>	<i>B. (animalis) lactis CNCM I-2494</i>	1B/serving	1-3 servings							I (136,137)	I (138)	
<b>DanActive®*</b>	<i>L. casei sp. Paracasei CNCM I-1518</i>	10B/serving	1-2 servings	II (139-141)	I (142)		I (143-146)		I (144)			I (147-154)
<b>GoodBelly® Probiotic Juice Drinks</b>	<i>L. plantarum 299v</i>	20B/serving (8 oz)	1 serving						III (22)	I (24-26)		
<b>Nestlé® Gerber® Baby Cereals</b>	<i>B. lactis BB-12</i>	1B/serving	1 serving			I (112,155)	I (112,155)					
<b>Nestlé® Good Start® Probiotic with PRO-Blend™ 1</b>	<i>B. lactis BB-12</i>	130M/ 100mL serving	Routine feeding if an alternative to breast milk is required			I (113)						
<b>Nestlé® Good Start® 3 Toddler Transition Nutritional Supplement</b>	<i>B. lactis BB-12</i>	1B/200mL serving	1 serving			I (112,155)	I (112,155)					
<b>Nutramigen® A+® LGG® Extensively hydrolyzed casein formula (EHCF)</b>	<i>L. rhamnosus GG</i> Branded LGG	1.35x10 <sup>7</sup> CFU per 100mL serving	EHCF when an alternative to breast milk is required						I (156-158)			

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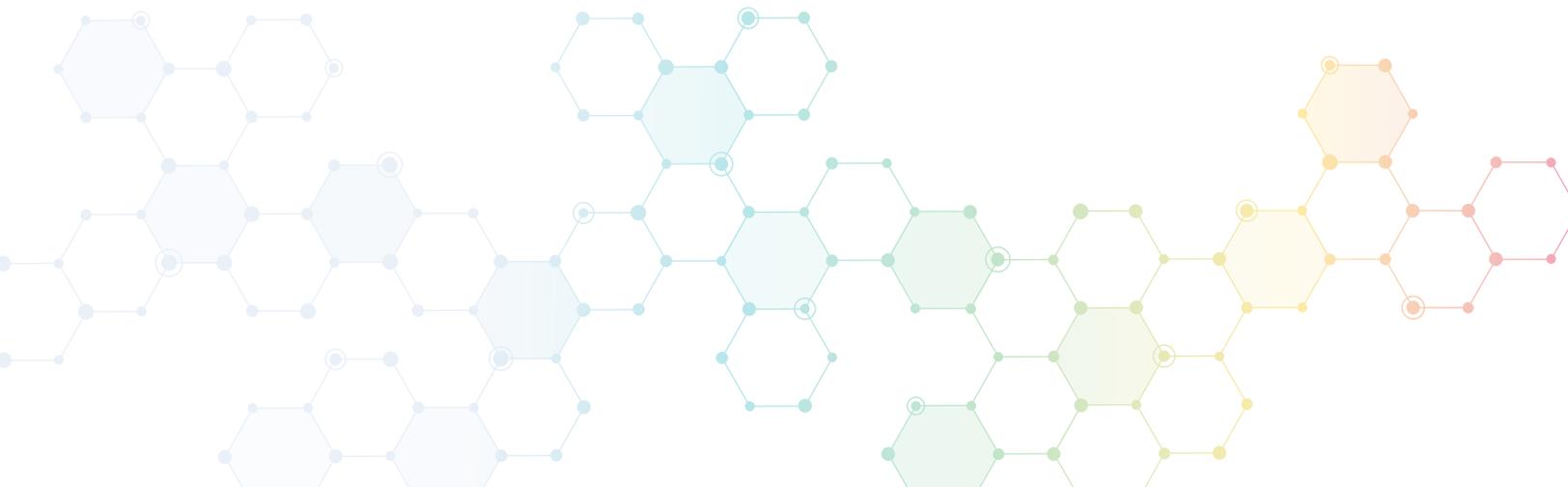
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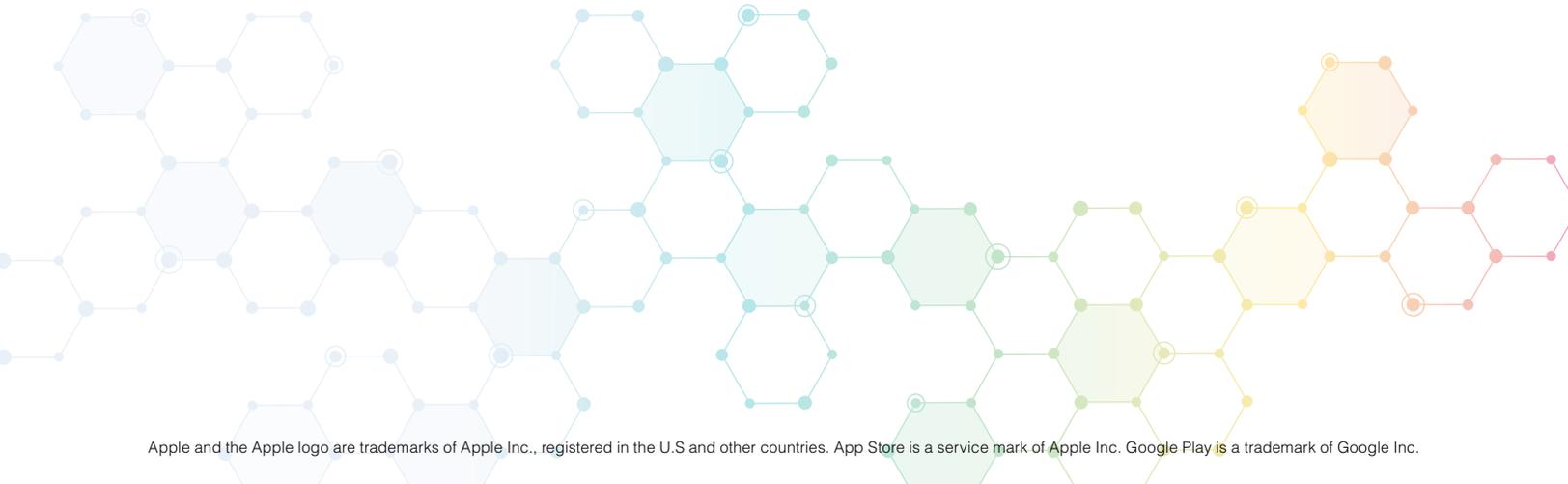
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