

1
NEW
INDICATION
FOR 2016

Clinical Guide to **PROBIOTIC SUPPLEMENTS**

AVAILABLE IN CANADA: 2016 Edition

Indications, Dosage Forms, and Clinical Evidence to Date

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PURPOSE AND METHODS

PURPOSE:

This guide is designed to translate scientific evidence available for probiotic supplements into practical, clinically relevant information, enabling clinicians to easily select the appropriate product, dose, and format for a specific indication.

METHODS:


Published data or studies with defined clinical outcomes for probiotic strain(s) were searched, using inclusion criteria as listed in the guide. Commercially available products containing said strain(s) were identified, and the modified levels of evidence were used to rate the strength of the recommendation for each product. Once this information was compiled into a comprehensive chart form, it was assessed by independent expert reviewers.

Readers are strongly encouraged to review the evidence listed for each product for themselves.

DISCLAIMER: Information in this guide is not intended to diagnose, treat, cure, or prevent any disease. This guide is meant to be used as a clinical decision making tool to assist health care professionals in providing evidence based recommendations for their patients. In the case of probiotics, the clinical evidence supports only certain formulations/brand names of the probiotics (including the genus, species, alphanumeric designation or strain, number of live bacteria present, the blend of probiotic strains present and finally, the non-active ingredients present). Every attempt was made by the author and the reviewers to include the published clinical data for the available probiotic formulations. No bias is intended toward any specific formulation. 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 the Alliance for Education on Probiotics (AEP). We are grateful for the unrestricted publishing grant the AEP is providing for continuous efforts to translate science into clinically applicable forms.

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ACRONYMS

AAD	Antibiotic associated diarrhea - Prevention	IBD-UC	IBD - Ulcerative colitis – Adjunct to standard therapy
BG	Reduces blood glucose in Type II Diabetes (FBG and HA1c)	IBS	Irritable bowel syndrome
C	Constipation	ID	Infectious diarrhea
CDAD	<i>Clostridium difficile</i> associated diarrhea - Prevention	LDL-C	Reduces LDL and total cholesterol
CE/AD	Childhood eczema/Atopic dermatitis	NEC*	Necrotizing Enterocolitis (newborn) *as per hospital protocol, not for self-administration
CID	Common infectious disease	NI	Nosocomial infections prevention
FAP	Functional abdominal pain	OH	Oral health 
HP	<i>Helicobacter pylori</i> - Adjunct to standard eradication therapy	Regurg/ GI Mot	Reduces regurgitation/Improves gastrointestinal motility
IBD-P	Inflammatory bowel disease - Pouchitis	TD	Traveler's diarrhea

CFU = Colony forming units (number of viable bacteria), M = million, B = billion, *L.* = *Lactobacillus*, *B.* = *Bifidobacterium*

INCLUSION CRITERIA AND LEVELS OF EVIDENCE

ALL 3 MUST BE SATISFIED:

1. Commercially available in Canada as a supplement or probiotic-containing food
2. GRAS - Generally Recognized as Safe status (FDA) and/or NPN - 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/food

NOTE:

- For products containing multiple strains, evidence must be for the specified combination and not for the separate probiotic strains
- Some products are excluded from the current edition due to changes in strains used
- Please refer to individual publications for specifics of patient populations studied and details of clinical effect (age and gender)

LEVEL I: Evidence obtained from at least one properly-designed randomized trial. (HIGHEST LEVEL).

LEVEL II: 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 centre 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.

LEVEL III: Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.

INDICATIONS FOR ADULT HEALTH

Brand Name	Probiotic Strain(s)	Dosage Form	CFU/dose	No. of doses/day	ID	AAD	CDAD	TD	C	IBS	IBD-UC	IBD-P	HP	OH	LDL-C	CID
Align®	<i>B. longum infantis</i> 35624	Capsule	1B/capsule	1 capsule						I ¹⁻⁴						
Bio-K+® CL1285 ⚠	<i>L. acidophilus</i> CL 1285 <i>L. casei</i> LBC80R <i>L. rhamnosus</i> CLR2	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 1/2 -1 tub 1/2 -1 tub 1/2 -1 tub		I ⁵⁻⁷	I ⁶⁻⁹									
BioGaia® chew tabs	<i>L. reuteri</i> DSM 17938	Chew. tab	100M/tab	1 tab	II ¹⁰	II ¹¹			I ¹⁶				II ¹²⁻¹⁵			
BioGaia® drops	<i>L. reuteri</i> DSM 17938	Drop	100M/5 drops	5 drops	II ¹⁰	II ¹¹			I ¹⁶				II ¹²⁻¹⁵			
CardioViva™	<i>L. reuteri</i> NCIMB 30242	Capsule	2B/capsule	2 capsules											I ¹⁷⁻¹⁹	
CulturedCare™ ProbioticGum	<i>Streptococcus salivarius</i> K12	Lozenge	0.5B/lozenge	2-10 lozenges										II ^{44,45}		
Culturelle®	<i>L. rhamnosus</i> GG	Capsule	10B/capsule	1 capsule		I ²⁰							I ²¹			
Digestive Care™ Daily Relief	<i>L. plantarum</i> 299v	Capsule	10B/capsule	1 capsule		III ²²	III ²³			I ²⁴⁻²⁶						
Digestive Care™ Diarrhea Relief	<i>L. rhamnosus</i> GG	Capsule	10B/capsule	1 capsule		I ²⁰							I ²¹			
Florastor®	<i>Saccharomyces boulardii</i> lyo	Capsule Sachet	5B/capsule 5B/sachet	1-2 capsules 1-2 sachets		I ^{27,28}	I ^{8,9,28,29}	I ³⁰⁻³²				III ³³		I ³⁴⁻³⁶		
HMF by Genestra™	<i>L. acidophilus</i> CUL60 <i>L. acidophilus</i> CUL21 <i>B. bifidum</i> CUL20 <i>B. lactis</i> CUL34	Capsule Forte Capsule Intensive Capsule Super Powder	2.5B/capsule 10B/capsule 25B/capsule 10B/1 scoop (1 gram)	1-2 capsules 1-2 scoops			II ³⁷			II ³⁸						
IbSium®	<i>Saccharomyces cerevisiae</i> I-3856	Capsule	40B/capsule	1 capsule						I ³⁹						
Mutaflor® ⚠	<i>Escherichia coli</i> Nissle 1917	Capsule	2.5-25B/ capsule	1-2 capsules								I ⁴⁰⁻⁴³				

⚠ - Product requires refrigeration

INDICATIONS FOR ADULT HEALTH

Brand Name	Probiotic Strain(s)	Dosage Form	CFU/dose	No. of doses/day	ID	AAD	CDAD	TD	C	IBS	IBD-UC	IBD-P	HP	OH	LDL-C	CID
PerioBalance™	<i>L. reuteri</i> ATCC 55730 <i>L. reuteri</i> ATCC PTA 5289	100M 100M Lozenge	200M/lozenge	2 lozenges										46,47		
Proxiflor® (formerly Lacidofil)	<i>L. rhamnosus</i> R0011 <i>L. helveticus</i> R0052	Capsule	4B/capsule	1-3 capsules						148						
TuZen®	<i>L. plantarum</i> 299v	Capsule	10B/capsule	1-2 capsules		122	123			24-26						
Ultra Probiotic Complex by GNC	<i>L. acidophilus</i> CUL60 <i>L. acidophilus</i> CUL21 <i>B. bifidum</i> CUL20 <i>B. lactis</i> CUL34	Packet Capsule	25B/packet 25B, 50B, 75B/capsule	1-2 packets 1-2 capsules			37			38						
UltraFlora™ Cold Support (formerly Health Defense)	<i>L. plantarum</i> HEAL9 <i>L. paracasei</i> 8700:2	0.5B 0.5B Capsule	1B/capsule	1 capsule												49,50
Visbiome™ ❄️	<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					61		52-54	53,55-57				
VSL#3® ❄️	<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	1-4 sachets					61		52-54	53,55-57				

❄️ - Product requires refrigeration

INDICATIONS FOR PEDIATRIC HEALTH

Brand Name	Probiotic Strain(s)	Dosage Form	CFU/dose	No. doses/day	Regurg/ GI Mot	NEC* (newborn)	Colic	ID	AAD	CDAD	IBD-UC	HP	C	IBS	FAP	CID	NI	CE/AD	OH
BioGaia® chew tabs	<i>L. reuteri</i> DSM 17938	Chew. tab	100M/tab	1 tab	§58-60		¶62-65	¶66-70	¶71				¶72,73	¶74,75	¶74,75	¶76,77		¶78	
BioGaia® drops	<i>L. reuteri</i> DSM 17938	Drop	100M/ 5 drops	5 drops	§58-60	¶61	¶62-65	¶66-70	¶71				¶72,73	¶74,75	¶74,75	¶76,77		¶78	
CulturedCare™ ProbioticGum	<i>Streptococcus salivarius</i> K12	Lozenge	1B/lozenge	1-5 lozenges															¶¶44,45
Culturelle®	<i>L. rhamnosus</i> GG	Powder	5B/packet	2-4 packets				¶79-84	¶85,86					¶87,88	¶87,88		¶89	¶90-96	
Digestive Care™ Diarrhea Relief Kids	<i>L. rhamnosus</i> GG	Powder	5B/packet	1-2 packets				¶79-84	¶85,86					¶87,88	¶87,88		¶89	¶90-96	
Florastor®	<i>Saccharomyces boulardii</i> lyo	Capsule Sachet	5B/capsule 5B/sachet	1-2 capsules 1-2 sachets				¶98-100	¶101	¶¶102		¶¶35							
HMF Fit for School™ [50 mg vitamin C]	<i>L. acidophilus</i> CUL21 <i>L. acidophilus</i> CUL60 <i>B. lactis</i> CUL34 <i>B. bifidum</i> CUL20	Tablet	12.5B/tablet	1 tablet												¶103			
Junior Daily Probiotics (formerly DDS® Junior)	<i>B. lactis</i> UABLA-12 4.2B <i>L. acidophilus</i> DDS®-1 0.8B	Powder	5B/gram	2 grams												¶¶104		¶105	
Probiotic Baby	<i>B. lactis</i> BB-12	Drop	1B/6 drops	6 drops					¶107							¶106			
Proxilfor® (formerly Lacidofil)	<i>L. rhamnosus</i> R0011 <i>L. helveticus</i> R0052	Capsule	4B/capsule	1 capsule														¶¶108	

* as per hospital protocol, not for self-administration

INDICATIONS FOR PEDIATRIC HEALTH

Brand Name	Probiotic Strain(s)	Dosage Form	CFU/dose	No. doses/day	Regurg/ GI Mot	NEC* (newborn)	Colic	ID	AAD	CDAD	IBD-UC	HP	C	IBS	FAP	CID	NI	CE/AD	OH	
Ultimate FLORA™ ☼ (formerly FloraBABY)	<i>B. breve</i> HA-129 1.2B <i>L. rhamnosus</i> HA-111 1B <i>B. bifidum</i> HA-132 0.8B <i>B. infantis</i> HA-116 0.6B <i>B. longum</i> HA-135 0.4B	Powder	4B/scoop	1 scoop		1197														
UltraFlora™ Baby	<i>L. rhamnosus</i> GG <i>B. lactis</i> BB-12	Drop	1B/6 drops	6 drops												1109				
UltraFlora™ Children's	<i>L. acidophilus</i> NCFM® 2.5B <i>B. animalis</i> subsp <i>lactis</i> Bi-07 2.5B	Chewable tablet	5B/chew. tablet	1-2 chew. tablets												1110				
Visbiome™ ☼	<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				1111			1112,113			1114						
VSL#3® ☼	<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				1111			1112,113			1114						

☼ - Product requires refrigeration

* as per hospital protocol, not for self-administration

INDICATIONS FOR VAGINAL HEALTH

Brand Name	Probiotic Strain(s)	Dosage Form	CFU per dose	No. of doses/day	Vulvovaginal candidiasis	Bacterial vaginosis
Fem-Dophilus®	<i>L. rhamnosus</i> GR-1 2.5B <i>L. reuteri</i> RC-14 2.5B	Oral capsule	5B/capsule	1 capsule	^{115,116}	¹¹⁷⁻¹¹⁹
ProB™ (RePhresh ProB)	<i>L. rhamnosus</i> GR-1 2.5B <i>L. reuteri</i> RC-14 2.5B	Oral capsule	5B/capsule	1 capsule	^{115,116}	¹¹⁷⁻¹¹⁹
Probiac BV®	<i>L. acidophilus</i> A-212 0.4B <i>L. rhamnosus</i> A-119 6.8B <i>S. thermophilus</i> A-336 0.8B	Vaginal capsule	8B/capsule	1-2 capsules		¹²⁰
Provacare™	<i>L. rhamnosus</i> Lcr35	Vaginal capsule	3.41B/capsule	2 capsules	¹²¹	¹²²⁻¹²⁴
Purfem™	<i>L. rhamnosus</i> PB01 1B <i>L. gasseri</i> EN-153471 (EB01) 1B	Vaginal ovule	2B/ovule	1 ovule		^{125,126}
UltraFlora™ Women's	<i>L. reuteri</i> RC-14 1B <i>L. rhamnosus</i> GR-1 1B	Oral capsule	2B/capsule	2 capsules	¹²⁷	^{128,129}

FUNCTIONAL FOODS WITH ADDED PROBIOTICS

Brand Name	Probiotic Strain(s)	CFU/dose	No. of doses / day	Children				Adults					
				ID	HP	AAD	CID	AAD	IBS	HP	C	BG	CID
Activia® ❄️	<i>B. (animalis) lactis</i> CNCM I-2494	1B/serving	1-3 servings						^{150,151}		¹⁵²		
DanActive® ❄️	<i>L. casei</i> sp. <i>Paracasei</i> CNCM I-1518	10B/serving	1-2 servings	¹⁵³⁻¹⁵⁵	¹⁵⁶		^{157,159,140}	¹³⁸					¹⁴¹⁻¹⁴⁸
iOGO Probio™ ❄️	<i>B. lactis</i> BB-12 <i>L. acidophilus</i> LA-5	1B/100g	1-3 servings							¹⁵⁰⁻¹⁵³	^{154,155}	¹⁵⁶	
Nestlé® Gerber® Graduates Infant Cereals	<i>B. lactis</i> BB-12 DSM 10140	1B/28g serving	1 serving			^{106,149}	^{106,149}						
Nestlé® Gerber® Graduates Toddler Cereals	<i>B. lactis</i> BB-12 DSM 10140	1B/35g serving	1 serving			^{106,149}	^{106,149}						
Nestlé® Gerber® Graduates Toddler Drink	<i>B. lactis</i> BB-12 DSM 10140	1B/200mL serving	1 serving			^{106,149}	^{106,149}						
Nestlé® Good Start® Probiotic Infant Formula	<i>B. lactis</i> BB-12 DSM 10140	130M/100mL serving	Routine feeding if an alternative to breast milk is required			¹⁰⁷							
Yoptimal® ❄️	<i>B. lactis</i> BB-12 <i>L. acidophilus</i> LA-5	1B/100g	1-3 servings							¹⁵⁰⁻¹⁵³	^{154,155}	¹⁵⁶	

❄️ - Product requires refrigeration

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