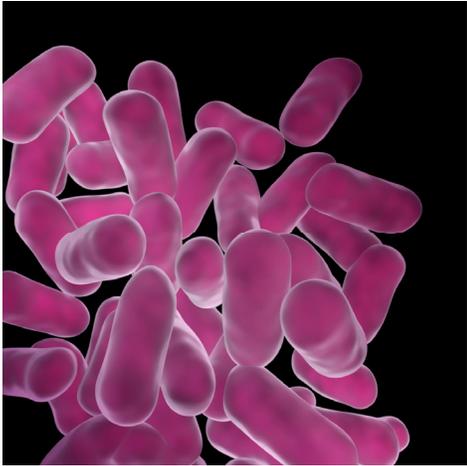


# get the facts

## Oral Probiotics: An Introduction



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Probiotics are live microorganisms (e.g., bacteria) that are either the same as or similar to microorganisms found naturally in the human body and may be beneficial to health. Also referred to as “good bacteria” or “helpful bacteria,” probiotics are available to consumers in oral products such as dietary supplements and yogurts, as well as other products such as suppositories and creams. The U.S. Food and Drug Administration (FDA) has not approved any health claims for probiotics. This fact sheet provides a general overview of probiotics, with an emphasis on oral products, and suggests sources for additional information.

### Key Points

- Probiotic products are widely marketed, and consumer interest in probiotics is growing rapidly. Although some probiotic formulations have shown promise in research, strong scientific evidence to support specific uses of probiotics for most conditions is lacking.
- Probiotics have potential applications in many areas of human health, and research to gather scientific evidence about whether and how they work is moving forward. Additional clinical studies are needed to investigate the safety and efficacy of probiotics for specific uses.
- If you are thinking about using a probiotic dietary supplement, consult your health care provider first. Probiotics—like any form of complementary medicine—should not be used in place of conventional medical care or to delay seeking care if you are experiencing symptoms that concern you.
- Tell all your health care providers about any complementary approaches you use. Give them a full picture of what you do to manage your health. This will help ensure coordinated and safe care.

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## Background

The concept behind probiotics was introduced in the early 20th century, when Nobel laureate Elie Metchnikoff, known as the “father of probiotics,” proposed in *The Prolongation of Life: Optimistic Studies* that ingesting microorganisms could have substantial health benefits for humans. Microorganisms are invisible to the naked eye and exist virtually everywhere. Scientists continued to investigate the concept, and the term “probiotics”—meaning “for life”—eventually came into use.

Picturing the human body as a “host” for bacteria and other microorganisms is helpful in understanding probiotics. The body, especially the lower gastrointestinal tract (the gut), contains a complex and diverse community of bacteria. (In the body of a healthy adult, cells of microorganisms are estimated to outnumber human cells by a factor of ten to one.) Although we tend to think of bacteria as harmful “germs,” many bacteria actually help the body function properly. Most probiotics are bacteria similar to the beneficial bacteria found naturally in the human gut.

Various mechanisms may account for the effects of probiotics on human health. Possible mechanisms include altering the intestinal “microecology” (e.g., reducing harmful organisms in the intestine), producing antimicrobial compounds (substances that destroy or suppress the growth of microorganisms), and stimulating the body’s immune response.

Probiotics commonly used in the United States include *Lactobacillus* and *Bifidobacterium*. There are many specific types of bacteria within each of these two broad groups, and health benefits associated with one type may not hold true for others.

### Probiotics, Prebiotics, and Synbiotics

Probiotics are not the same as prebiotics—nondigestible substances that stimulate the growth and/or activity of potentially beneficial microorganisms. The term “synbiotics” refers to products that combine probiotics and prebiotics.

## Use of Probiotics in the United States

In the United States, probiotics are available as dietary supplements (including capsules, tablets, and powders) and in dairy foods (such as yogurts with live active cultures). According to the 2007 National Health Interview Survey, which included questions on Americans’ use of natural products other than vitamins and minerals, “prebiotics/probiotics” ranked fifth among natural products used for children, but were not among the top-ranking products for adults. Although probiotic products are more popular in Europe and Japan than in the United States, the U.S. consumer market for probiotics is growing rapidly.

Although the FDA has not approved any health claims for probiotics, they are used for a variety of gastrointestinal conditions such as infectious diarrhea, diarrhea associated with using antibiotics, irritable bowel syndrome, and inflammatory bowel disease (e.g., ulcerative colitis and Crohn’s disease). Probiotics are also being used for preventing tooth decay and for preventing or treating other oral health problems such as gingivitis and periodontitis. Some—but not all—probiotic formulations have been widely studied and show considerable promise. However, the rapid

growth in marketing and consumer interest and use has outpaced scientific research on the safety and efficacy of probiotics for specific health applications.

### **Government Regulation of Probiotics**

Government regulation of probiotics is complex. Depending on a probiotic product's intended use, the FDA might regulate it as a dietary supplement, a food ingredient, or a drug. Many probiotic products are sold as dietary supplements, which do not require FDA approval prior to marketing. Dietary supplement labels may make claims about how the product affects the structure or function of the body without prior FDA approval, but they cannot make health claims (claims that the product reduces the risk of a disease) without the FDA's consent. (For more information about dietary supplements, see *Using Dietary Supplements Wisely* at [nccam.nih.gov/health/supplements/wiseseuse.htm](http://nccam.nih.gov/health/supplements/wiseseuse.htm).) A product that is marketed as a drug must meet more stringent requirements. It must be proven safe and effective for its intended use through clinical studies (tests in people) and be approved by the FDA before it can be marketed.

### **Status of Probiotics Research**

The potential of probiotics to benefit human health in many different ways has stimulated great interest and activity among researchers. For example, the National Center for Complementary and Alternative Medicine (NCCAM) is part of the National Institutes of Health (NIH) Probiotic and Prebiotic Working Group, a trans-NIH effort to identify gaps and challenges in prebiotic/probiotic research.

Probiotic research is moving forward on two fronts: basic science (laboratory studies) and clinical trials to evaluate the safety and efficacy of probiotics for various medical conditions. Many early clinical trials of probiotics have had methodological limitations, and definitive clinical evidence to support using specific probiotic strains for specific health purposes is generally lacking. Nevertheless, there is preliminary evidence for several uses of probiotics, and more studies are under way. In particular, a recent review of the scientific evidence on the effectiveness of probiotics in acute infectious diarrhea concluded that there was evidence that probiotics can shorten the duration of diarrhea and reduce stool frequency but that more research was needed to establish exactly which probiotics should be used for which groups of people.

In 2008, the journal *Clinical Infectious Diseases* published a special issue on probiotics, which included an overview of clinical applications. Based on a review of selected studies, the authors classified several applications according to the strength of evidence supporting the efficacy of probiotics in prevention and/or treatment. For example, the authors concluded that strong evidence exists for acute diarrhea and antibiotic-associated diarrhea, and substantial evidence exists for atopic eczema (a skin condition most commonly seen in infants). Promising applications include childhood respiratory infections, tooth decay, nasal pathogens (bacteria harbored in the nose), gastroenteritis relapses caused by *Clostridium difficile* bacteria after antibiotic therapy, and inflammatory bowel disease. The authors also discussed various potential future applications.

Studies also indicate that probiotics may reduce side effects associated with treatment for *Helicobacter pylori* infection, the cause of most stomach ulcers. A systematic review suggests that

there is strong evidence that probiotics may reduce the risk of necrotizing enterocolitis, a severe intestinal condition of premature newborns. Other potential future applications include use in reducing cholesterol levels, treating obesity, and managing irritable bowel syndrome.

## **Safety and Side Effects**

It appears that most people can use probiotics without experiencing any side effects—or with only mild gastrointestinal side effects such as gas—but there have been some case reports of serious adverse effects, and research on safety is ongoing. A 2008 review of probiotics safety noted that *Lactobacillus rhamnosus* GG has been widely studied in clinical trials for a variety of conditions and generally found to be safe. Nevertheless, a recent review of *Lactobacillus* and *Bifidobacterium* biology noted that long-term, cumulative effects of probiotics use, especially in children, are unknown, and also pointed to evidence that probiotics should not be used in critically ill patients. Similarly, a 2011 Agency for Healthcare Research and Quality assessment of the safety of probiotics, partly funded by NCCAM, concluded that the current evidence does not suggest a widespread risk of negative side effects associated with probiotics. However, the data on safety, particularly long-term safety, are limited, and the risk of serious side effects may be greater in people who have underlying health conditions.

Concerns have also been raised about the quality of probiotic products. Some products have been found to contain smaller numbers of live microorganisms than expected. In addition, some products have been found to contain bacterial strains other than those listed as ingredients.

## **If You Are Thinking About Using Probiotics**

- Our understanding of probiotics is a work in progress. Although probiotic products are marketed for many different uses, scientific evidence supporting specific uses is still limited, and the FDA has not approved any health claims for probiotics. Before using probiotics, learn as much as you can by talking to your health care provider and researching reliable sources of information.
- Different probiotic products may contain different types of probiotic bacteria. Different types of probiotic bacteria may have different effects in the human body, and effects also may vary from person to person.
- Probiotics—or any form of complementary medicine—should not be used in place of conventional medical care or to delay seeking care if you are experiencing symptoms that concern you. If you are pregnant or nursing or are planning to give probiotics to a child, consulting your (or your child’s) health care provider is especially important. Anyone with a serious underlying health problem should be monitored closely for potential negative side effects while taking probiotics.
- Tell all your health care providers about any complementary and alternative approaches you use. Give them a full picture of what you do to manage your health. This will help ensure coordinated and safe care. For tips on talking with your health care providers about complementary and alternative medicine, see NCCAM’s Time to Talk campaign at [nccam.nih.gov/timetotalk/](http://nccam.nih.gov/timetotalk/).

## NCCAM-Funded Research on Probiotics

Recent NCCAM-supported research on probiotics has included clinical studies<sup>1</sup> focused on:

- Prevention and treatment of diarrhea in infants
- Potential benefits for adults and children with irritable bowel syndrome and for people with minimal hepatic encephalopathy (a complication of liver disease)
- Treatment of an antibiotic-resistant type of bacteria
- Yogurt beverages as a way of giving high doses of probiotics to young children.

NCCAM also supports laboratory studies that explore possible mechanisms of action for probiotics, providing a foundation for clinical research. For example, recent studies have found evidence that a strain of *Lactobacillus reuteri* might slow the growth of certain tumors, and that *Lactobacillus acidophilus* might enhance the effects of a vaccine against rotavirus infection—the most common cause of infectious diarrhea in infants and children worldwide.

NCCAM's clinical research program has designated probiotics as a high-priority topic for upcoming projects. Studies will focus on probiotics for addressing gastrointestinal disorders in infants and children, including necrotizing enterocolitis, colic, and irritable bowel syndrome; treating and preventing antibiotic-induced diarrhea; and enhancing the effects of flu vaccine.

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<sup>1</sup> NCCAM-supported clinical research includes studies conducted under FDA-approved investigational new drug applications. Before these studies can proceed to medically vulnerable populations, researchers carry out rigorous trials to determine safety in healthy adults or people with mild medical conditions.

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## For More Information

### NCCAM Clearinghouse

The NCCAM Clearinghouse provides information on NCCAM and complementary medicine, including publications and searches of Federal databases of scientific and medical literature. The Clearinghouse does not provide medical advice, treatment recommendations, or referrals to practitioners.

Toll-free in the U.S.: 1-888-644-6226

TTY (for deaf and hard-of-hearing callers): 1-866-464-3615

Web site: [nccam.nih.gov](http://nccam.nih.gov)

E-mail: [info@nccam.nih.gov](mailto:info@nccam.nih.gov)

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Web site: [www.ncbi.nlm.nih.gov/sites/entrez](http://www.ncbi.nlm.nih.gov/sites/entrez)

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