Supplements to help manage total cholesterol, LDL and HDL

Glucomannan

COMMON NAME: Glucomannan

SCIENTIFIC NAME: Amorphophallus konjac

NOT RECOMMENDED - HIGH RISK

LEVELS OF EVIDENCE

Recommended:

Several well-designed studies in humans have shown positive benefit. Our team is confident about its therapeutic potential.



Not Recommended - Evidence:

Our team does not recommend this product because clinical trials to date suggest little or no benefit.



Recommended with Caution:

Preliminary studies suggest some benefit. Future trials are needed before we can make a stronger recommendation.



Not Recommended - High Risk:

Our team recommends against using this product because clinical trials to date suggest substantial risk greater than the benefit.

Evaluated Benefits

No evidence of efficacy or not indicated



Source

Raw glucomannan is a soluble, fermentable, and highly viscous dietary fiber from the elephant yam or konjac plant, native to Asia. Konjac glucomannan (KGM) is water soluble and a viscous dietary fiber due to its high water absorbing capacity. The chemical structure of glucomannan consists in an 8:5 mannose:glucose ratio, linked by b-glycosidic bonds, making raw glucomannan the highest molecular weight and viscosity of any other known dietary fibers.

The very high viscosity led to a choking hazard with konjac-containing candies, and numerous FDA warnings and recalls (see partial list added to the end of this document). This is why any marketed supplements that may contain konjac would be a hydrolyzed, nonviscous version that does not provide the health effects associated with the high-viscosity version.

Indications/Population

Patients with high total and LDL cholesterol for the raw version only, which has a significant choking hazard

Mechanism of Action

Glucomannan improved blood lipid levels by enhancing fecal excretion of neutral sterol; and bile acids bind biliary salts, taking the blood lipids with them.

Lipid-lowering action may include an inhibition of cholesterol absorption in the jejunum (19) and bile acid absorption in the ileum (33) mediated by viscosity or less postprandial stimulation of 3-hydroxy-3-methylglutaryl-CoA reductase.

Raw glucomannan is thought to prolong gastric emptying time, which increases satiety, reduces body weight, decreases the ingestion of foods that increase cholesterol and glucose concentrations, reduces the postprandial rise in plasma glucose, suppresses hepatic cholesterol synthesis, and increases the fecal elimination of cholesterol-containing bile acids. There is no evidence that nonviscous versions more commonly marketed in the U.S. provide any health effects.

Side Effects

Gastric discomfort, loose stools, flatulence, and diarrhea are the most commonly reported side effects.

Dosing

1.2–15.1 grams daily for up to 12 weeks, administered in various forms, including as capsules, tablets, bars, biscuits, and refined konjac meal, has been studied.

Nonviscous glucomannan has been safely used in children for up to 4 months at 1–1.5 grams BID (twice a day).

It is recommended that KGM should not be taken in association with medications or other supplements that have hypoglycemic effects. Oral medications should be taken one hour before or four hours after ingesting KGM capsules.





Drug Interactions/Cautions

In tablet form, there have been reports of esophageal and gastrointestinal obstruction, as well as choking to the point of causing obstruction. Advise patients to use glucomannan in powdered or capsule form (nonviscous, no health effects).

Glucomannan displays no evidence of psychotropic activity, but now has considerable choking hazard.

Notes

See FDA warnings/recalls referenced below. Extreme caution advised about recommending this fiber. In its raw form, it is dangerous. In its nonviscous form, it is safe but useless — no gel-dependent health effects.

Since 1994, KGM has been approved as a food additive by the U.S. Food and Drug Administration (FDA). In 1996 it was also passed as a binder in meat and poultry products by the U.S. Department of Agriculture (USDA). In Europe, KGM has been given an E425 agreement number by the European Food Safety Authority (EFSA). KGM has also been used in controlled drug delivery systems and in the production of absorbent materials, such as disposable diapers and sanitary napkins.

There are no adverse effects on the absorption of iron, calcium, copper, and zinc. On the contrary, low-density glucomannan with low molecular weight often has many impurities, such as sulfites, heavy metals, arsenic, and other little dark particles that cause lower hypocholesterolemic activity and a bad smell.

References

Cleveland Clinic

Wellness

Chuaa M, Baldwin TC, Hocking TJ, Chan K. Traditional uses and potential health benefits of Amorphophallus konjac. *Journal of Ethnopharmacology*. 2010; 128(2): 268–278. **doi: 10.1016/j.jep.2010.01.021**

Chutkan R, Fahey G, Wright WL, McRorie J. Viscous versus nonviscous soluble fiber supplements: mechanisms and evidence for fiber-specific health benefits. *Journal of the American Academy of Nurse Practitioners*. 2012; 24(8): 476–487. doi: 10.1111/j.1745-7599.2012.00758.x

Guardamagna O, Abello F, Cagliero P, Visioli F. Could dyslipidemic children benefit from glucomannan intake? *Nutrition*. 2013; 29(7–8): 1060–1065. **doi: 10.1016/j.nut.2013.02.010**

Martino F, Martino E, Morrone F, Carnevali E, Forcone R, Niglio T. Effect of dietary supplementation with glucomannan on plasma total cholesterol and low-density lipoprotein cholesterol in hypercholesterolemic children. *Nutrition, Metabolism & Cardiovascular Diseases*. 2005; 15(3): 174–780. doi: 10.1016/j.numecd.2004.04.004

Sood N, Baker WL, Coleman CL. Effect of glucomannan on plasma lipid and glucose concentrations, body weight, and blood pressure: systematic review and meta analysis. *American Journal of Clinical Nutrition*, 2008; 88(4): 1167–1175.

Vuksan V, Sievenpiper JL, Owen R, Swilley JA, Spadafora P, Jenkins DJ, et al. Beneficial effects of viscous dietary fiber from konjac-mannan in subjects with the insulin resistance syndrome. *Diabetes* <u>Care</u>. 2000; 23(1): 9–14.



Konjac Candy — FDA Issues Warnings to Public and Import Alert FDA Issues Second Warning of Danger of Choking on Konjac Candy

On October 5, 2001, the FDA issued a second warning to the public concerning the serious choking hazard caused by konjac candy. The FDA issued the first warning on August 17, 2001. Konjac candy is a fruit-flavored gel candy in various flavors that is imported primarily from Asia and has been linked to six deaths in children in the United States. The FDA decided a second warning was warranted after consultation with experts on choking from the Consumer Product Safety Commission (CPSC). CPSC staff confirmed that these candies posed a serious choking risk, particularly to infants, children, and the elderly. The FDA also issued an import alert to address the problem of importation of these candies from other countries. The agency worked with numerous firms in a nationwide recall of these candies. One firm, New Choice, refused to recall their candies and the product was seized by the FDA following repeated attempts to get the firm to recall the candies.

Numerous Recalls of Konjac Candy

- The FDA announced a recall by Thomas Diaz Inc. of Toa Baja, Puerto Rico, of 1,500 cartons of Fruzel assorted Natural Fruit Jelly Candy because these products present a choking hazard. The product was distributed to wholesale and retail establishments throughout Puerto Rico under the Neo USA brand. The mini jelly candies came in assorted flavors. Each mini jelly cup is about the size of single-serve coffee creamer. The candies were packaged in 16.5-gram jars with 88 units per jar.
- On May 17, 2002, the FDA announced a recall by Everlasting Distributors Inc. of Bayonne, New Jersey, of 1,197 cases of mini jelly candies (or mini cup gel candy) because these products presented a choking hazard. The product was distributed to retail establishments throughout New York, Massachusetts, Illinois, Florida, Georgia, Maryland, New Jersey, Pennsylvania, and Virginia under the ABC brand.
- On April 25, 2002, the FDA announced a recall by Yoli Inc. of Chicago, Illinois, of 3,115 bags of mini jelly candies (or mini cup gel candy) because these products present a choking hazard. The product was distributed in bags that read, in part, "Mi Costenita...Gelatinas Coconut Jelly" to retail establishments in Illinois, Michigan, Ohio, Indiana, Tennessee, Arkansas, Missouri, Mississippi, Kansas, Alabama, Georgia, North Carolina, and Wisconsin.
- On April 25, 2002, the FDA announced a recall by Lien Hoa Food Corp. of Chicago, Illinois, of 464 cases of mini jelly candies (or mini cup gel candy) because these products present a choking hazard. The product was distributed to retail establishments throughout northern Illinois and Wisconsin under the Jojomo and Naluwan brands. The label described the product as "JM Jojomo" and "Naluwan Nata De Coco Konnyaku Jelly" in all flavors. The candy came in small, creamer-size sealed plastic cups.
- On April 5, 2002, the FDA announced recalls from G. L. Food Wholesale Inc. of City of Industry, California, and Philippine Foodtrade Corporation of Vernon, California, of 100 cases of mini jelly candies (or mini cup gel candy) because these products present a choking hazard. The product was distributed to retail establishments throughout southern California under the Sugarland brand. The label described the product as "Jellyace Buko Pandan." The candy came in small sealed plastic cups.





- On February 15, 2002, the FDA reported a recall by Golden Country Oriental Food of Chicago, Illinois. These candies were distributed in Illinois, Iowa, Indiana, Kentucky, Ohio, Wisconsin, Florida, Michigan, Missouri, South Dakota, and Kansas. The three brand names included Don Empire, another with no brand name and only Chinese characters and butterflies on the label, and My Love and Coco. The individual serving cups were packaged in 300-gram plastic bags with 30 bags per case, 510-gram plastic panda-bear-shaped jars with 12 jars per case, and 1,200-gram round plastic jars with 6 jars per case. Golden Country Oriental Food requested a recall through its distributors and retailers to consumers, who were urged to return this product to the place of purchase.
- Five Continents,Ltd. of Chicago, Illinois, recalled konjac candies that were distributed in Indiana, Illinois, Nebraska, Michigan, Kentucky, Ohio, Wisconsin, Missouri, Texas, Iowa, New Jersey, Kansas, and South Dakota. The name was ABC brand Konjac Coconut Jelly Mini Fruit Bites Candy. The individual serving cups were packaged in 300-gram plastic bags with 30 bags per case and 1,500-gram plastic round and panda-bear-shaped jars with 6 jars per case. Consumers were urged to return this product to the place of purchase.
- On January 30, 2002, the FDA announced the recall by Anhing Corporation of Los Angeles, California, of Rolin brand Lychee Nata De Coco Jelly because this product presents a choking hazard. These candies were distributed nationwide. The candies were packaged in small sealed plastic cups. Each mini jelly cup was about the size of a single-serve coffee creamer.
- January 15, 2002, the FDA announced a recall by Walong Marketing Inc., of Buena Park, California, of Mini Jelly Snack Cups because this product presents a choking hazard. These candies were distributed nationwide and internationally under the brands Kimbo, Asian Taste, Jin Jin, and Shen Hsiang Jen Foods. The candies were packaged in small sealed plastic cups.
- On December 7, 2001, the FDA announced the recall of approximately 16,000 packages of mini cup gel candies because they present a choking hazard. This candy, distributed nationwide to retail establishments, was sold under the names of Mother's Pride and NATA, and the label described the product as a "mini-fruit bite." The candy came in small sealed plastic cups that contained gelatin with or without a chunk of fruit.

On July 23, 2002, the FDA's Philadelphia District Office announced that Santi and Sons of Reading, Pennsylvania, initiated a recall of mini gel candies and issued a press release to alert the public of the potential choking hazard associated with the product. On July 30, 2002, the district witnessed the destruction of 960 cases of mini gel candies with an approximate value of \$15,360. The recalled candies were disposed at Conestoga Landfill, Morgantown, Pennsylvania. These candies were sold under the following brand names: New Choice Mini Fruit Gels, Yummy Choice Fruit Gel Snacks, and Sheng Hsiang Jen Conjac Coconut Jelly. These candies were sold in the following flavors: apple, grape, taro, lychee, peach, pineapple, mango, orange, lemon, strawberry, and assorted flavors. Santi and Sons retrieved the recalled product from their consignees and destroyed the recovered product. The district monitored the recall until completion.





Konjac Candy Voluntarily Destroyed

On February 20, 2002, the FDA's Chicago District Office investigators and the City of Chicago Department of Public Health cooperatively witnessed the voluntary destruction of 1,390 cases of 30 300-gram plastic bag containers and 1,392 cases of 6 1,500-gram plastic jar containers of ABC Mini Jelly candies under embargo at Five Continents in Chicago, Illinois. The candy included products collected from Five Continents and embargoed product at an affiliated sister firm under the same ownership, Wu Chu of Chicago, Illinois, following inspections of the firms.

The recalled products were part of the konjac candies being recalled as a choking hazard. The value of the destroyed products was \$39,687.80. Five Continents anticipated continued receipt of recalled products from their sub accounts.

Seizure of "Konjac" Candy

Firm Fails to Recall Candy Which Causes Choking —Product Is Seized

On May 22, 2002, New Choice Food's mini gel candies were seized at the firm's facility in Irwindale, California. The FDA took this action after the agency determined that the candies presented a serious choking hazard. Prior to the seizure, the state of California was holding the products under an embargo. FDA scientists and staff physiologists from the Consumer Product Safety Commission concluded that the packaging, shape, slipperiness, and consistency of the products all contributed to the product's inherent choking potential. Thus, the articles are adulterated under 21 U.S.C. § 342(a) (3) of the Federal Food, Drug, and Cosmetic Act (the Act), in that they are unfit for food because they pose a serious choking hazard.

These candies contained an ingredient konjac (also known as congac, konnyake, yam flour, or glucomannan) and, unlike gelatin products, do not readily dissolve when placed in the mouth.

Numerous companies have recalled these konjac candies. New Choice, however, did not recall their candies. The FDA conducted an inspection of the firm in Irwindale, California, in January 2002. The company failed to cease distribution of the product and to voluntarily recall product currently on the market.

Under these circumstances, seizure of the goods was necessary. The FDA issued a letter to the U.S. Attorney requesting that a Complaint for Forfeiture be filed in the U.S. District Court. The Complaint charged that the products were adulterated within the meaning of 21 U.S.C. § 342(a)(3), and misbranded within the meaning of 21 U.S.C. §§ 343(a)(1), 343(i)(1), 343(i)(2), and 343(r)(1)(A) of the Act, and adulterated within the meaning of 21 U.S.C. § 342(a)(3).

Each gel cup was about the size of a single-serve coffee creamer. The gel cups were sold in 250-gram (8.75-ounce) and 300-gram (10.5-ounce) plastic bags or in 1,100-gram (38.5-ounce) and 1,500-gram (52.5-ounce) plastic jars. Some labels of these products bore a warning suggesting that they are a choking hazard, and some labels stated that they should not be consumed by children of various ages, ranging from 3 to 6 years of age.



