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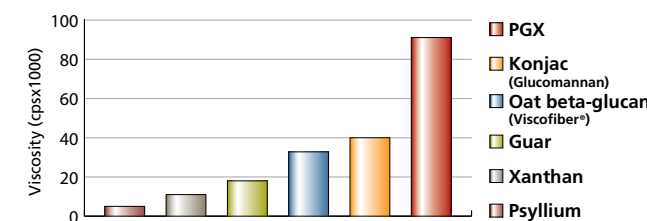
PGX<sup>®</sup> US PATENT 8062686

( PolyGlycopleX<sup>®</sup> )

## Frequently Asked Questions about PGX<sup>®</sup> (PolyGlycopleX<sup>®</sup>) for Healthcare Professionals

### What is PGX<sup>®</sup>?

PolyGlycopleX<sup>®</sup> (α-D-glucurono-α-D-manno-β-D-manno-β-D-gluco), (α-L-gulurono-β-D-mannurono), β-D-gluco-β-D-mannan), more commonly known as PGX<sup>®</sup>, is a unique highly-purified, water-soluble polysaccharide (fibre) developed from natural ingredients using advanced EnviroSimplex<sup>®</sup> technology. The three starting ingredients are combined in a very specific ratio and act synergistically to develop a higher level of viscosity than any other dietary viscous fibre currently known (Figure 1). Unlike many fibre-containing natural health products, PGX<sup>®</sup> does not lose its gel-like viscosity in either acidic stomach or alkaline intestinal environments, despite these drastic changes in pH.



**Figure 1:** Viscosity of PGX<sup>®</sup> compared to other water soluble polysaccharides after hydrating for 3 hours. Measurements up to 90000 cps were taken with spindle 3. \*PGX<sup>®</sup> viscosity not less than 90000 cps. (Cole Parmer Viscometer 98936 series, C=1.4%)

### How is PGX<sup>®</sup> an improvement over other fibre supplements/products on the market?

PGX<sup>®</sup> is much more than a fibre source due to its viscosity. PGX<sup>®</sup> is easy to use, natural, colourless, and has no distinctive odour or taste. PGX<sup>®</sup> maintains its viscosity throughout the entire digestive tract for optimum effectiveness. Some fibres are non-thickening and therefore cannot provide the health benefits of PGX<sup>®</sup>. Others thicken too quickly and can make foods and beverages unpalatable. PGX<sup>®</sup> granules thicken at a much slower rate, so they are easily incorporated into foods and beverages. No single fibre or fibre blend can match the science, research or viscosity on a weight for weight basis for the effectiveness of PGX<sup>®</sup>.

### What are the physiological benefits of PGX<sup>®</sup>?

The physiological benefits exerted by PGX<sup>®</sup> relate to its nature as a highly viscous polysaccharide (gel-like fibre) with a very high water holding capacity. Mixing PGX<sup>®</sup> with food or

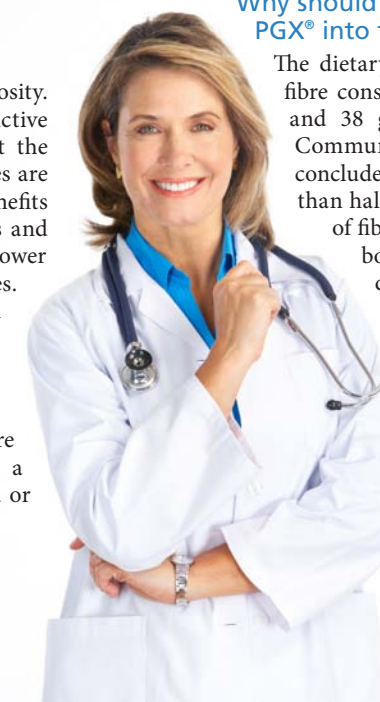
beverages increases its thickness or viscosity, thereby increasing the volume of gastric content. This promotes an early sense of satiety even when food portions are decreased. PGX<sup>®</sup> also slows down and prolongs digestion and the absorption of any food down the gastrointestinal tract. This leads to beneficial effects, such as extending after-meal satiety and a normalization of postprandial blood glucose and insulin excursions. This effect is in keeping with research demonstrating that the greater a fibre's viscosity, the more effective it will be in reducing the glycemic response to foods.<sup>1</sup>

In the colon, PGX<sup>®</sup> is highly prebiotic, and therefore is readily fermented into healthful short-chain fatty acids, substances important to colon health,<sup>2</sup> lipid metabolism<sup>3</sup> and appetite control.<sup>4</sup> As a viscous polysaccharide, PGX<sup>®</sup> also increases excretion of fecal bile acids. With lower levels of bile in the blood stream, additional bile acids are produced by the liver from blood cholesterol, lowering blood cholesterol levels.

As a result of these positive metabolic effects, adding sufficient quantities of soluble fibres like PGX<sup>®</sup> to one's daily intake over time is an excellent way to improve both overall health and reduce the risk of developing chronic diseases like cardiovascular disease and diabetes.

### Why should my patients incorporate PGX<sup>®</sup> into their diet?

The dietary reference intake for total daily fibre consumption is 25 grams for women and 38 grams for men.<sup>5</sup> The Canadian Community Health Survey Cycle 2.26 concluded that most individuals eat less than half the daily recommended amount of fibre. Adding sufficient quantities of both soluble and insoluble fibre to daily intake is an excellent way to improve both overall health and reduce the risk of developing chronic diseases like heart disease and diabetes. However, despite the widely known health benefits of consuming such viscous fibres, getting a consistent amount in



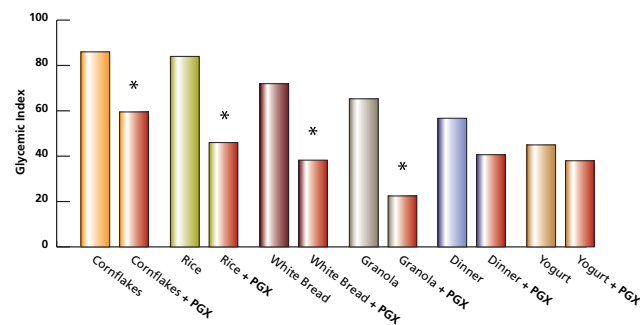
the daily diet may pose a challenge for some Canadians. One easy and convenient way to add more viscous soluble fibre to the diet is through the use of PGX®.

### What research is there to support PGX® benefits and effectiveness?

PGX® is the result of many years of intensive clinical and laboratory research in collaboration with universities from around the world, specialized research organizations and with the Canadian Centre for Functional Medicine. After years of research involving thousands of participants, it is clear that adding PGX® to meals can improve blood glucose levels, reduce the glycemic index of foods, restore insulin sensitivity (a key factor in weight control), reduce hunger and food intake, assist in weight management, and lower cholesterol levels.

#### Health benefits of PGX include:

- Improved postprandial glycemia (lowering the glycemic index of foods up to 50%) (Figure 2)<sup>7,8,9,10</sup>
- Lowered LDL and total cholesterol levels<sup>3,11,12</sup>
- Reduced risk factors associated with the Metabolic Syndrome<sup>13,14,15</sup>
- Reduced hunger<sup>16</sup> and food intake<sup>17</sup>
- Healthy weight loss of 0.25-0.5 kgs (0.5 to 2 lbs.) per week<sup>11,18</sup>



**Figure 2:** Reductions of the glycemic index when PGX® is added or incorporated into commonly consumed foods. \*Statistically different than food without PGX® (p<0.001)<sup>8</sup>

### Who should add PGX® to their diets?

The people who would benefit from PGX® include individuals who want to:

- Reduce their risk of developing diabetes and/or cardiovascular disease
- Prevent Metabolic Syndrome and lower insulin resistance
- Improve and better manage blood glucose levels
- Improve cholesterol levels, whether or not they are on cholesterol-lowering medication
- Lose weight, prevent weight gain, or prevent weight regain after weight loss (maintenance)

### What dosage of PGX® should my clients/patients take per day?

To attain the full benefits of PGX®, clients/patients should take PGX® with every meal. Start with 1-2 softgels of PGX® Daily or

2.5 grams of PGX® Granules at one meal. Gradually add PGX® to more meals every 2-3 days until portion size and between-meal food cravings are decreased. It is important to drink at least 250 mL (8 fl oz) of water per 2.5 gram serving of PGX®. If your client/patient is prone to digestive upset, slow the rate that the dose is increased by to give their body time to adjust.

Some people find as few as 3 softgels of PGX® Daily or 2.5 grams of PGX® Granules per meal to be effective. Others require the maximum dose of 6 softgels of PGX® Daily or 5 grams of PGX® Granules per meal.

A successful approach to weight loss and then weight management is to consume a PGX® Meal Replacement shake twice a day, in place of breakfast and lunch. After your clients/patients initial weight loss goals are met, suggest they can eat two regular, healthy meals each day and continue to use the PGX® Meal Replacement once per day. PGX® Daily softgels or PGX® Granules could be consumed with food instead of the Meal Replacement to help maintain a healthy weight.

### What are the common side effects of PGX®?

PGX® is highly concentrated and a highly effective form of fibre. It can take time for the body to adjust to the increased amounts of dietary fibre and PGX® is no exception to this rule. To minimize side effects, such as gas, loose stools, transient diarrhea, abdominal discomfort, bloating and constipation, it is best to start with small amounts of PGX® and gradually increase the intake as the body adjusts.

If your client's diet is low in fibre, have them start on a low dose of PGX® and increase the amount very gradually. Start with 2.5 grams once per day as a starting dose and gradually increase to achieve target levels. Some people start on the full dose (10-15 grams per day) and experience no adverse effects. It is important for people to understand the possible side effects and that results can vary.

If your client/patient takes PGX® consistently and increases the dose gradually, it is almost certain that they will be able to consume a highly effective dose within a few days to a couple of weeks. Be sure they drink plenty of water with or immediately after each PGX® serving. Side effects are greatly minimized by consuming enough water – between 375 and 500 mL (12-16 fl oz) per 5 grams.

### Are there any contraindications with common medications?

PGX® can slow the rate of absorption of food and therefore it can theoretically do the same with medication. It is recommended that any oral medication be taken 1 hour before PGX® and/or 2 to 3 hours after consuming PGX® products.

People with diabetes must monitor their blood glucose carefully as they may need to adjust medications accordingly. As PGX® helps control blood glucose, it may lessen the need for medication or insulin over time.

If your client/patient has to take their oral medication with breakfast, suggest they can take PGX® at lunch and dinner time or with a mid morning health snack. If your client is taking an array of medications, it may be appropriate to recommend that they consult with their physician prior to taking PGX®.

### How safe is PGX® and does it affect mineral and vitamin bioavailability?

In addition to being a highly effective and practical product, PolyGlycopleX® (PGX®) is very safe to consume. A number of safety and toxicity studies have been done in both animals and humans.<sup>12,19,20</sup> A double blind randomized placebo controlled study performed in humans showed the product to be very well tolerated. These results as well as a thorough review of data by a panel of experts and a group of consulting toxicologist in the USA resulted in PGX® receiving self-affirmed “Generally Recognized As Safe” (GRAS) and Medical Food classification. This confirms that adding PGX® to food is considered safe by experts.

Besides being safe, PGX® does not affect mineral or vitamin bioavailability or cause malabsorption. A 21-day double blind, placebo controlled human tolerance study where 10 grams of PGX® was given per day showed no statistical difference between levels of mineral, fat-and water-soluble vitamins between the test and control groups.<sup>8</sup>

Phytic acid from cereal fibres or insoluble, non-viscous, dietary fibres have been found to depress the absorption and retention of several minerals.<sup>21</sup> Since PGX® does not contain phytic acids, it is unlikely to affect mineral bioavailability. However, a vitamin and mineral supplement is recommended if your client's diet does not meet their nutritional needs.

### Who should not use PGX®?

- Anyone who cannot compensate for a large intake of water, such as individuals with renal diseases and congestive heart failure.
- Anyone on a large number of medications that need to be taken with food and/or without food unless advised by a physician.
- Persons with gastrointestinal disorders who have difficulty swallowing, esophageal stenosis or pre-existing bowel abnormalities (such as gastrointestinal strictures or impaired mobility) as they may be at risk for throat or esophageal blockage or bowel obstruction. Individuals with any gastrointestinal diseases or who have undergone gastrointestinal surgeries should consult their physician before taking PGX®.
- Pregnant or lactating women should discuss PGX® prior to use with their health care professional.

### Is PGX® simply a weight loss diet product or food fad?

PGX® isn't a diet but it can make any sensible weight loss/management plan or diet work better. PGX® is easy to apply and can be used as a healthy supplement at home, on vacation, in a restaurant and at dinner with friends.

Eating a healthy balanced diet is always recommended, but for successful weight loss many people need simple and practical help. Although there are many key considerations in a healthy weight management program including developing healthy



behaviours, portion control and increased physical activity, PGX® may assist by reducing hunger, improving satiety, (feeling satisfied longer), stabilizing blood glucose, improving insulin sensitivity and lowering cholesterol levels.

### What if a client taking PGX feels too full to eat?

If PGX® is reducing your client's hunger and appetite so much that it is causing them to starve their body by consuming too few calories and thereby slowing down their metabolism, they may need to reduce the amount of PGX® they are consuming.

In general for weight loss, it is recommended to consume a minimum of 1200-1400 calories each day because it has been shown to be nutritious, yet allows for the calorie deficit most people require for losing weight. Standard diet programs recommended by medical professionals and nutritionists use 1200-1400 calories as a foundation when developing meal plans.

PGX® helps people modify food intake and portion size, helping them control their hunger and appetite so that they eat less, easily. For weight loss, encourage smaller meals and healthy snacks between meals to keep the metabolism running well throughout the day.

### Can PGX® be taken long-term?

Yes. PGX® can be used long-term like many other types of viscous, soluble, and functional dietary fibres. In fact, PGX® has been proven safe in published studies, is self-affirmed GRAS and over the last 6 years nearly half a billion single servings of PGX® have been sold with minimal adverse events, reinforcing its safety for daily use. Furthermore, the key ingredients from which PGX® is manufactured all have CODEX E numbers and have been used as food ingredients and additives for ten's to hundreds of years.

PGX® can be employed as both a preventative agent to help reduce the risk factors associated with certain types of chronic diseases (i.e. Type 2 diabetes, cardiovascular, Metabolic Syndrome), as well as positively modify certain laboratory values associated with these latter conditions.

PGX® must be taken on a continual basis in order to achieve the same beneficial health affects seen with other types of dietary modifications.

*For health care professionals, PGX® is available through Bioclinic Naturals. PGX® is also distributed by Natural Factors through health food stores and by Webber Naturals found in grocery stores and pharmacies.*

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