# N ORTH CENTURY PHARMACY Distributed By: North Century Pharmacy 3058 Campbellsville Rd Columbia, KY 42728

VITALITY MI

#### NORTH CENTURY PHARMACY

#### Clinical Applications

- Provides Nutrients Associated With Detoxification Mechanisms\*
- Supports Gastrointestinal Health\*
- Supports Balanced Cytokine Activity\*
- Lactose-Free Vegan Protein Source\*
- Provides High-Quality Macro- and Micronutrients\*

Vitality Mix is formulated to support the body's natural response to toxic substances by providing high-quality macro- and micronutrients associated with detoxification mechanisms. Many of these nutrients also cooperatively foster gastrointestinal health and balanced cytokine activity—important variables in the body's handling of toxic substances. This advanced formula features of Vegan Protein Blend, North Century Pharmacy's proprietary amino acid and pea/rice protein blend; Aminogen® provides proteases, which facilitate protein absorption; activated B vitamins like 5-MTHF and patented mineral amino acid chelates for optimal nutrient bioavailability; and key herbal extracts and phytonutrients. Vitality Mix is a low-allergy-potential, monk fruit-sweetened formula that boasts a superior taste without added sugars or stevia and is suitable for vegans.\*

All North Century Pharmacy Formulas Meet or Exceed cGMP Quality Standards

#### Discussion

Persistent bioaccumulative toxicants originate from various industrial and agricultural practices and processes. These toxicants linger in soil, air, water, and dust for long periods and can be inhaled into the lungs, absorbed via the skin, or consumed through the food chain. Additionally, over 10,000 chemicals are allowed in US food products. Some of these chemicals are direct additives (eg, artificial colors, preservatives), while others are indirect additives that contaminate food during processing, storage, and packaging.¹ Exposure to and an accumulation of such toxicants within the body pose significant health risks to humans, including endocrine disruption, neurological effects, immune system dysfunction, and cell-cycle disturbances.² The physiological process of detoxification—mobilization, modification, and excretion of exogenous and endogenous toxicants—transforms primarily nonpolar, lipid-soluble toxicants into polar, water-soluble, and excretable derivatives.³ The steps in molecular detoxification pathways are classified as phase I, which is mediated primarily by cytochrome P450 (CYP450) enzymes, and phase II, which is mediated by conjugation enzymes.\*

Various macro- and micronutrients are used in these phases of detoxification. Furthermore, adequate nutrient levels—including vitamins, minerals, antioxidants, and amino acids—are essential for mitochondrial function and play crucial roles in energy metabolism and adenosine triphosphate (ATP) production. As the chief contributor of free energy in all biological systems, ATP fuels all biochemical reactions, including detoxification reactions.\*

Vitality Mix is a comprehensive micro-/macronutrient formula providing key antioxidants, herbal extracts, and other nutritional compounds used by the body to fuel detoxification processes. This formulation features detox- and GI-friendly nutrients as well as cytokine cascade-targeting ingredients because toxicants can interfere with the body's immune system, leading to enduring changes in the body's cytokine profile.\*

#### Pomegranate Extract (Punica granatum)

Pomegranate extracts have been studied for their cytokine-balancing and antioxidant properties in animals and humans.<sup>4,5</sup> The pomegranate extract in Vitality Mix is standardized to 30% ellagitannins, specifically punicalagins A + B and punicalins A + B; these reference substances speak to the consistency of the extract batch to batch. Ellagitannins are a distinctive group of bioactive polyphenols found in pomegranates. Punicalagin, which is exclusively present in pomegranates, is the largest-molecular-weight polyphenol known and is acclaimed for its potent antioxidant properties.<sup>6</sup> After ingestion, punicalagin is metabolized in the body to urolithins and ellagic acid, the latter being a natural phenolic antioxidant known for its support of antioxidant—detoxification processes.\*<sup>7</sup>

#### Betaine

Betaine, also known as trimethylglycine, is a naturally occurring vital methyl donor for methylation reactions.<sup>8</sup> Methylation is a pathway in phase II detoxification mechanisms.<sup>9</sup> Betaine regulates the methionine cycle and homocysteine detoxification through betaine homocysteine methyltransferases. Furthermore, betaine is key in the S-adenosylmethionine to S-adenosylhomocysteine ratio in liver cells and helps maintain normal methylation activity.<sup>8</sup> Betaine also synthesizes glutathione via the transsulfuration pathway.\*<sup>10</sup>

#### Lemon Bioflavonoid Complex

Citrus bioflavonoids, which are found in citrus fruit peels, seeds, and juice, play pivotal protective roles within the human body. These bioflavonoids act as potent scavengers of free radicals and have the potential to regulate cytokine production.<sup>11</sup> For instance, in vitro studies focusing on various citrus bioflavonoids have revealed their ability to inhibit prostaglandin E-2, the secretion of proinflammatory cytokines, and the expression of NF-κB, showcasing their potential health benefits.\*\*11-13

#### Rutir

Rutin, a prominent bioflavonoid also known as vitamin P or rutoside, has demonstrated diverse biological activities related primarily to its high free radical–scavenging activity and antioxidant capacity. Also Rutin has also demonstrated metal-chelating action, which involves the formation of complexes with metal ions—a process crucial for preventing free radical generation that can harm essential biomolecules. In the colon, probiotic bacteria metabolize rutin, producing quercetin and rutin metabolites that yield beneficial antioxidants.

#### Quercetin

Quercetin is a phytochemical belonging to the flavonoid class of polyphenols that confers a wide range of benefits to human health. <sup>18,19</sup> These benefits are primarily mediated through quercetin's antioxidant activities and effects on the immune system. <sup>18</sup> In vitro and in vivo studies have demonstrated that the primary antioxidant mechanisms of quercetin include directly scavenging free radicals, chelating metal ions, inhibiting lipid peroxidation, regulating glutathione levels, and impacting enzyme activities and signal transduction pathways. <sup>\*18</sup>

Continued on next page

\*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

#### Turmeric

Turmeric has been used for its medicinal properties for nearly 2,500 years, originating from the Vedic culture in India.<sup>20,21</sup> Curcuminoids are active compounds within turmeric, responsible for its vibrant color and a host of its biological activities.<sup>20</sup> Roles of turmeric/curcuminoids in digestive support, the growth of beneficial gut flora, healthy bowel transit time, and detoxification enzyme activities have been noted through traditional use and tested through scientific research.\*<sup>20,23</sup>

#### Ginger

Ginger, derived from the rhizome of *Zingiber officinale*, offers a myriad of health benefits primarily attributed to bioactive compounds, such as gingerols and shogaols. Scientific research demonstrates that ginger inhibits proinflammatory cytokines, such as IL-1β and TNF-α, while suppressing COX and LOX enzymes, key contributors in the inflammatory process.<sup>24</sup> Moreover, ginger's potent antioxidant capabilities neutralize free radicals, providing cellular protection against oxidative stress.<sup>24</sup> Historically, ginger has been used as an antiemetic and carminative. As a bitter herb, ginger also encourages efficient digestion.\*<sup>25</sup>

#### Methylsulfonylmethane (MSM)

MSM, also known as methyl sulfone and dimethyl sulfone, is a naturally occurring organosulfur compound in various fruits, vegetables, grains, and animal tissues. Sulfur, the seventh most abundant element in the body, is involved in vital metabolic pathways, including carbohydrate metabolism, protein synthesis, redox balance, and detoxification.<sup>26</sup> Meeting dietary sulfur requirements may be impacted by poor or restrictive diets or increased needs, such as in disease states. Supplemental MSM can help to fill such nutritional gaps.<sup>26</sup> MSM has been studied extensively for its influence on oxidative stress and proinflammatory mediator production.<sup>27,29</sup> Like MSM, the sodium sulfate in Vitality Mix also serves as a source of sulfur.\*

#### Green Tea

Green tea is rich in polyphenols, particularly catechins such as epigallocatechin gallate (EGCG), which is considered the most abundant and effective among them. Green tea catechins play pivotal roles in combating oxidative stress by enhancing the body's antioxidant enzyme levels and neutralizing harmful radicals, including superoxide and hydrogen peroxide.<sup>30</sup> These catechins have also garnered attention for their potential to mitigate DNA damage and support cellular health by modulating various biological pathways and detoxification enzyme activities, thereby offering protection against oxidative stress and toxicant-induced cellular damage.\*30.32

#### N-Acetyl-L-Cysteine (NAC)

NAC is a form of the amino acid cysteine, which the liver uses to synthesize the antioxidant glutathione. Glutathione is a major phase 2 conjugating constituent, wherein glutathione S-transferases attach a glutathione group to a phase 1 biotransformed metabolite to enable excretion.<sup>9,33,34</sup> Therefore, a reduced glutathione status potentially impacts phase 2 glutathione conjugation reactions.\*

#### Vegan Protein Blend

North Century Pharmacy's Vegan Protein Blend protein is a proprietary blend of non-GMO pea protein concentrate, pea protein isolate, rice protein concentrate, taurine, glycine, and L-glutamine. This easy-to-digest protein has a well-balanced amino acid profile, including essential branched-chain amino acids, and is high in lysine and arginine. Protein contributes amino acids, which play vital roles in detox physiology: amino acids serve as building blocks for phase 1 CYP450 enzymes and are required to conjugate intermediate metabolites during phase 2 detoxification processes. 9.33 Additionally, a consistent amino acid supply is necessary for the biosynthesis of glutathione, which has a critical role in phase 2 glutathione conjugation of physiologic metabolites (eg, estrogen) and xenobiotics. \*35

#### Aminogen®

Aminogen is a naturally derived, patented blend of fungal proteases derived from *Aspergillus niger* and *Aspergillus oryzae*. Aminogen contributes to enhanced protein absorption and reduced protein excretion when combined with protein consumption, and it helps the body naturally liberate free-form amino acids.\*

#### Preventium® (Potassium D-glucarate)

Potassium D-glucarate is a source of glucaric acid, a phytochemical produced in small amounts by the body and naturally found in fruits and vegetables, such as apples, grapefruit, Brussels sprouts, and broccoli. 3.57 Glucaric acid has gained attention for its potential role in cellular detoxification processes. The primary mechanism of glucaric acid is beta-glucuronidase inhibition. Beta-glucuronidase is an enzyme that separates conjugated toxicant moieties. 3 By inhibiting beta-glucuronidase, glucaric acid helps prevent toxicants from being reabsorbed and contributes to their elimination. 3 To further elucidate the roles of glucaric acid in detoxification, researchers performed an in silico efficacy analysis of glucaric acid on 4 molecular pathways involved in liver toxicity. The use of a computational systems biology platform demonstrated that glucaric acid reduced reactive oxygen species production in hepatocytes, lowered hepatic apoptosis, reduced beta-glucuronidase in hepatocytes, and decreased glucuronide deconjugate (toxins separated from conjugating glucuronide) levels in bile. 3 This in vitro work provides valuable insights for future animal and human studies to validate therapeutic uses of potassium D-glucarate. Diets low in fruits and cruciferous vegetables may result in a relative lack of glucaric acid, which would correlate with a higher level of beta-glucuronidase and possibly increase risks associated with toxicant accumulation.\*38

#### Micronutrients

Each phase of toxicant biotransformation depends upon a wide variety of micronutrients.<sup>9,33</sup> Phase 1 CYP450 enzymes and phase 2 methylation reactions require B vitamins and choline as enzyme cofactors.<sup>9,33,39</sup> Minerals, including selenium, copper, zinc, and manganese, and vitamins, such as A, C, and E, support antioxidant mechanisms that address the reactive oxygen species (intermediary metabolites) formed in phase 1 of biotransformation.<sup>9,33</sup> Other minerals, such as molybdenum, comprise enzymes (eg, molybdenum hydroxylases) that participate in phase 1 oxidation reactions.<sup>40</sup> Furthermore, micronutrients interact with nonessential metals, such as cadmium, lead, and mercury, at several points in the body; individuals consuming a micronutrientdeficient diet are predisposed to toxicity from nonessential metals.<sup>39</sup> To promote optimal absorption and utilization of micronutrients in Vitality Mix, vitamins and minerals are provided in bioactive forms: vitamins include Quatrefolic® (5- MTHF glucosamine salt), methylcobalamin, and pyridoxal 5'-phosphate. Minerals are provided as mineral amino acid chelates, which are digestive friendly, well tolerated, and have demonstrated greater bioavailability than their mineral salt counterparts.\*<sup>41,42</sup>

#### Golden Milled Flaxseed

As a source of fiber and omega-3 alpha-linoleic acid, flaxseed consumption helps to support a healthy gastrointestinal system. Related mechanisms include its potential to influence omega-3 concentration and roles in digestion and microbiota metabolism.<sup>43</sup> Flaxseed is also one of the richest sources of dietary lignans, including secoisolariciresinol diglucoside, which are known for their phytoestrogenic activity.<sup>44</sup> Flaxseed provides approximately 800-fold more lignans than most other food sources.\*<sup>45</sup>

#### No Added Sugar

Vitality Mix is sweetened with monk fruit (Siraitia grosvenorii)—a natural, high-potency sweetener approximately 200 to 300 times sweeter than sugar. Monk fruit's naturally occurring mogrosides (triterpene glycosides) impart its sweetness, and its overall phytochemical composition provides numerous health benefits, including antioxidant activity. 46 Unlike other sweeteners, monk fruit extract carries no bitter aftertaste and has zero calories at typical-use levels.\*

Vitality Mix is a robust formula that targets the body's natural detoxification mechanisms while fostering GI health and cytokine balance. These activities help to counteract the effects of persistent bioaccumulative toxicants and endogenous toxins that threaten human health.\*

#### Vanilla Delight

### Supplement Facts

Amo	unt Per Serving	%DV	Amoun	Per Serving	%D1
Calories	105		Sodium (from ingredients with naturally occurring sodium,	280 mg	12%
Total Fat	4 p	5%1	sodium sullate arrhydrous, and sodium ascerbate)		
Saturated Fat	1.0	5%1	Potassium (from tripotassium citrate and ingredients with	227 mg	5%
Total Carbohydrate	5 g	2%)	naturally occurring potassium)		
Dietary Fiber	2 g	7%	National States	190000	-
Protein (from Pea Protein Isolate and Rice Protein Concentrate)	13 g		Stabilized Flanseet Typical Alpha-Linolenic Acid	2.8 g 644 mg	
Vitamin A (as natural beta-carotene)	375 mcg	42%	Typical Aprile Lindenic Acid	198 mg	
Vitamin C (as sodium ascorbate)	125 mg	139%	Pomegranate Extract (Punica granatum)(whole fruit)	200 mg	**
Thiamin (as thiamine HCI)	7.5 mg	525%	(30% punkalagins A+B and punkalins A+B)	Zuo mg	
Riboflavin (as riboflavin 5 -phosphate sodium)	2.5 mg		Betaine Antivdrous (trimethylglycine)	125 ma	**
Nacin (as nacinamide and niscin)	20 mg		Lemon Biolayonoid Complex (Clinus + Amon) (fruit peel)	125 mg	
Vitamin B6 (as pyridoxal 5'-phosphate)	2.5 mg		(25% bioflavonoids)		
Fotate (as (65)-5-methyltetrahydrofolic acid,	170 mag DFE	43%	Quercetin (as quercetin sitrydrate from Dimorphandra molits)(pod)	125 mg	***
plucosamine salt) <sup>(1)</sup>			Potassium d-glucarate <sup>63</sup>	125 mg	**
Vitamin B12 (as methylcobalamin)	25 mcg	1,042%	Rutin (from Sophora Japonica)(bud)	100 mg	**
Biotin	.75 mcg	250%	Turmeric Edract (Curcuma longa) (rhizome) 95% total	100 mg	**
Parnothenic Acid (as d-calcium parnothenate)	17.5 mg		curcuminoids complex, including curcumin, curcuminoids, and		
Choline (as choline bitartrate)	50 mg	9%	volatile oils/(86% curcuminoids)(65% curcumin) <sup>rs</sup>		
Calcium (as dicalcium malate <sup>ss</sup> and	112 mg	9%	N-Acetyl-L-Cysteine	75 mg	***
ingredients with naturally occurring calcium)			Ginger (Zingiber officinale)(rhizome)	75.mg	**
Iron (naturally occurring)	2.5 mg		Methylsulfonylmethane (MSM)	60 mg	**
lodine (as potassium iodide)	30 mag	20%		50 mg	**
Magnesium (as di-magnesium malate) <sup>as</sup>	70 mg	17%	Green Tea Aqueous Extract (Camellia sinensis) (leaf)	41 mg	
Dinc (as zinc bisglycinate chelate) <sup>ko</sup>	5 mg	45%	(80% polyphenois, 60% catechins, 30% EGCG, 6% catteine)		
Selenium (as selenium glycinate ) <sup>(2)</sup>	50 mag		Linear and the second		
Manganese (as manganese bisplycinate chelate)33	1 mg	43%	Daily Value (DV) not established.		
Chromium (as chromium nicotinate glycinate chetate) <sup>12</sup>	30 mag	86%			
Molybdenum (as molybdenum glycinate chelate) <sup>cc</sup>	17.5 mcg	39%			

Other Ingrestients: Sunflower oil, natural flavors (no MSG), medium-chain triglyceride oil, taurine, glycine, cellulose gum, xanthan gum, fungal protasses, "L-glutamine, monifort, quar gum, and aliza.





trademarks of Balchem Corporation or its subsidi-

S3. Preventium® is a registered trademark of Applied Food Sciences, LLC.

S1. Quatrefolic s1. Quatrefolic is a registered trademark of Gnosis S.p.A. Produced under U.S. patent 7,947,662. A like of the Albino Cold Medallion are registered under U.S. patents 7,883,728, 7,736,679, and 7,879,373.



S5. AMINOGEN® is a registered trademark of Innophos Nutrition, Inc.

#### **Directions**

Blend, shake, or briskly stir 1 level scoop (26.5 g) into 5-6 ounces of chilled, pure water (or mix amount for desired thickness) and consume once daily, or use as directed by your healthcare professional.

Consult your healthcare professional prior to use. Individuals taking medication should discuss potential interactions with their healthcare professional. Do not use if tamper seal is damaged.

#### Formulated To Exclude

Wheat, gluten, yeast, soy, animal and dairy products, fish, shellfish, peanuts, tree nuts, egg, sesame, ingredients derived from genetically modified organisms (GMOs), artificial colors, and artificial sweeteners

‡This formula is not a low-calorie dietary supplement. Please see the Supplement Facts panel for more details.

Original Vitality Mix Vanilla: 210 Calories & 8 g fat/serv Vitality Mix Lite Vanilla: 105 Calories & 4 g fat/serv

#### Typical Amino Acid Profile Per Serving:

640 mg	Methionine	165 mg
1,290 mg	Phenylalanine	815 mg
1,700 mg	Proline	670 mg
150 mg	Serine	785 mg
2,495 mg	Taurine	250 mg
860 mg	Threonine	580 mg
370 mg	Tryptophan	150 mg
665 mg	Tyrosine	565 mg
1,245mg	Valine	745 mg
1,060 mg		
	1,290 mg 1,700 mg 150 mg 2,495 mg 860 mg 370 mg 665 mg 1,245mg	1,290 mg 1,700 mg 7 Proline 1,50 mg 2,495 mg 860 mg 3,70 mg 1,245 mg 1,245 mg Valine 1,245 mg

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- \*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.



### **BERBERINE 5X**

#### NORTH CENTURY PHARMACY

#### Clinical Applications

- · Supports Enhanced Berberine Activity\*
- Supports Healthy Blood Glucose Metabolism\*

**Berberine 5X** features dihydroberberine (DHB), a highly bioavailable metabolite of berberine with demonstrated benefits for blood glucose metabolism. Berberine naturally occurs in several plant species used extensively in traditional Ayurvedic and Chinese herbal practices; DHB is the natural bioactive form of berberine.\*

All North Century Pharmacy Formulas Meet or Exceed cGMP Quality Standards

#### Discussion

Berberine is a plant alkaloid derived from several different plant species customarily used in Ayurveda and traditional Chinese medicine for various therapeutic applications. Modern clinical use and published in vivo, in vitro, and animal research studies demonstrate that the berberine metabolite dihydroberberine (DHB) is more bioavailable than berberine and offers enhanced support for healthy blood glucose metabolism.\*1-5

Although the mechanisms underlying the beneficial effects of berberine are not entirely clear, it is hypothesized that the modulation of gut microbes may be one mechanism by which berberine affects blood glucose metabolism.<sup>6</sup> Results from animal and in vitro studies suggest that berberine moderates glucose and lipid metabolism through a multi-pathway mechanism, including the adenosine monophosphate—activated protein kinase (AMPK), c-Jun N-terminal kinase (JNK), and peroxisome proliferator-activated receptor (PPAR)-alpha pathways.<sup>2,7</sup> Separate research on AMPK reports activating the AMPK pathway stimulates glucose uptake and fat oxidation while suppressing lipogenesis and gluconeogenesis.<sup>8</sup> Berberine is also believed to be involved in the regulation of pancreatic beta cell function, and it has been observed to inhibit the expression of disaccharidases in the duodenum, resulting in less glucose formation from carbohydrate digestion.\*9

Increasing evidence indicates that gut microbiota are also crucial mediators that regulate berberine's pharmacokinetic and biological effects. Berberine induces compositional alterations in gut microbiota and regulates gut microbe—dependent metabolites, factors that contribute to its biological effects on lipid and glucose metabolism.<sup>10,11</sup> Additionally, gut microbiota reduce berberine to DHB, its intestine-absorbable form, which then oxidizes back to berberine after it has been absorbed into intestinal tissues and entered the blood.\*4

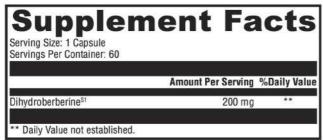
Berberine absorption across the intestinal epithelia is suggested to be compromised because of its "flat" chemical configuration. Berberine displays poor bioavailability and increased potential for GI distress at the oral doses required to improve biomarkers associated with glucose homeostasis. The structure of the DHB derivative of berberine is comparably open, making it more amenable to uptake. To further explore the absorbability of berberine and DHB, researchers investigated the mechanism of action by which AMPK is activated and if using DHB at lower doses than berberine could potentially improve the effect on adiposity and glucose metabolism in rodents fed a high-fat diet. Berberine had to be administered at a nearly 5-fold increased dose of 560 mg/kg/d to establish the same effects demonstrated by DHB at 100 mg/kg/d. The rodents treated with the substantially lower dose of DHB showed markedly reduced adiposity and improved glucose tolerance. Additionally, insulin sensitivity was increased in the DHB-treated animals. These results led researchers to suggest that the difference in effects between berberine and DHB is due to the enhanced bioavailability of DHB. The findings of this study indicate that DHB delivers the beneficial metabolic effects of berberine in a more absorbable form and at a lower dose.\*

A small, randomized, double-blind, crossover pilot study (N = 5) investigated the absorption kinetics and compared the dosing of berberine and DHB required to achieve peak plasma concentrations. Subjects completed a 4-dose protocol of placebo, 500 mg of berberine, 200 mg of DHB, and 100 mg of DHB. Participants ingested the first 3 doses with breakfast, lunch, and dinner, followed by an overnight fast, then a standardized test meal accompanied by dose 4. Blood samples were collected at regular intervals after ingestion and analyzed for berberine, glucose, and insulin. Four doses of 100 mg and 200 mg of DHB produced significantly greater concentrations of plasma berberine across the 2-hour measurement window than a 500-mg dose of berberine or placebo. Results suggest that irrespective of dose, DHB achieves a greater area under the curve and peak berberine concentrations when compared with oral ingestion of berberine.\*

North Century Pharmacy's **Berberine 5X** contains DHB originating from berberine sourced from *Berberis aristata* and naturally extracted through an enzymatic process similar to that which occurs in the human gut. With a 5-fold relative increase in absorption rate, supplemental DHB at much lower doses than berberine has comparable beneficial metabolic effects.\*4,5,12

\*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.





Other Ingredients: Microcrystalline cellulose, capsule (hypromellose and water), ascorbyl palmitate, and silica.



#### **Directions**

Take one capsule once or twice daily, or use as directed by your healthcare professional.

Consult your healthcare professional before use. Individuals taking medication should discuss potential interactions with their healthcare professional. Do not use if tamper seal is damaged.

#### Formulated To Exclude

Wheat, gluten, corn, yeast, soy, animal and dairy products, fish, shellfish, peanuts, tree nuts, egg, sesame, ingredients derived from genetically modified organisms (GMOs), artificial colors, artificial sweeteners, and artificial preservatives.

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\*These statements have not been evaluated by the Food and Drug Administration.
This product is not intended to diagnose, treat, cure, or prevent any disease.



# Distributed By: North Century Pharmacy 3058 Campbellsville Rd Columbia, KY 42728

#### NORTH CENTURY PHARMACY

#### Clinical Applications

- Supports Satiety\*
- Supports Weight Control\*
- Supports Glucose Metabolism\*
- Supports Cholesterol Metabolism\*
- · Supports Healthy Bowel Movements\*
- · Serves as a Prebiotic for Intestinal Bacteria\*

FiberLean Powder features Shimizu Propol® A propolmannan—a highly pure, natural soluble fiber. Propol A is created from Amorphophallus konjac-derived glucomannan using proprietary processing techniques. This fiber has been studied for its viscosity and for its stability through the digestive tract; and studies support its health effects, such as on satiety, weight control, glucose and lipid metabolism, and bowel regularity.\*

All North Century Pharmacy Formulas Meet or Exceed cGMP Quality Standards

#### Discussion

While a healthy diet and exercise are paramount to good health and maintaining healthy body composition, adding supplementary soluble fiber offers additional benefits. When selecting fiber, there are many aspects to review. Each fiber is unique in origin, purity, viscosity, and overall stability once ingested. In fact, even one type of fiber can vary greatly in quality. Amorphophallus konjac, a tuberous plant, is a rich source of the soluble fiber glucomannan. This fiber has an exceptional ability to absorb water and is one of the most viscous dietary fibers known.[1]

#### Not All Glucomannans Are Created Equal

There are many aspects of glucomannan that affect end-product quality: the species of konjac used, the harvesting location, the time of harvesting, the production process, impurities (e.g., sulfites), viscosity, the response of the viscosity to different pH levels and temperatures, and hydration speed. For these reasons, finding the material with the most manufacturing and processing experience and scientific research behind it is important.[1]

#### Propol® A Propolmannan

Shimizu Chemical Corporation is a pioneer in the world of dietary fiber and its health benefits. Using its vast knowledge—over 300 years of processing raw material (Japanese Amorphorphallus konjac species) and extracting glucomannan—it has developed Propol A propolmannan, a highly purified glucomannan. Shimizu's unique and proprietary three-stage purification process is carried out in large-scale extraction plants and involves pulverizing the Amorphophallus tubers, collecting mannan-glucose particles, and polishing the particles in order to dislodge and extract noxious materials that adhere to them. With the use of cutting-edge technology, Propol A has been reduced to a special particle size that maximizes density while remaining in desirable viscous form. This process yields a pure, refined, high-performance Amorphophallus propolmannan that improves product solubility, stability, and overall functionality.[1]

#### Viscosity, Stability Through the Digestive Tract

Viscosity is a physicochemical property of soluble fiber that reflects the fiber's ability to thicken as it mixes with fluid. Viscosity is a recognized factor affecting physiological responses to soluble fiber.[2] Propol A features an extremely high viscosity (100,000 mPa·s), which is thought to contribute to its health benefits.[1] Furthermore, as a benefit of its unique processing, Propol A remains intact in the digestive tract—another key factor in fiber functionality. Viscosity and stability, taken together, produce a highly effective material that, once in the digestive tract, attracts water and forms a viscous gel-like substance that slows digestion, delays the emptying of food from the stomach into the small intestine, slows down the influx of carbohydrates and fats into the bloodstream, binds to bile acids, and impedes dietary fat absorption.\* (3.4)

Soluble fiber is known to act as a bulking agent in the stomach and intestine, which creates the signals of fullness and causes individuals to eat less. [2,3,5,6] Studies suggest that glucomannan supplementation significantly reduces weight at doses of 3 g/d to 4 g/d when compared to placebo.[3,4,7,11] In a randomized, double-blind, placebo-controlled study, the effects of 3 g/d of Propol (1 g 30-60 minutes prior to each meal) combined with 300 mg/d of calcium were studied. When dosing compliant and non-complaint subgroups were analyzed, the results indicated that compliant subjects experienced a significant reduction in scale weight, body fat percentage, and fat mass without a loss of fat-free mass or bone density.[7] In another study, the mean weight loss for the glucomannan group was 5.5 lbs in eight weeks, while subjects in the placebo group gained 1.5 lbs.\*[3]

#### Glucose and Lipid Metabolism

Soluble fiber slows the absorption of carbohydrates, which influences the release of insulin and the rate of fat storage. Glucomannan studies have not only demonstrated a positive impact on postprandial glucose handling and glucose metabolism but also on cholesterol metabolism. [3,4,7,10-13] This latter effect is thought to result from the fact that soluble fiber reduces fat and cholesterol absorption and carries bile out of the intestines.[3,4] When fewer bile acids are available, the body draws cholesterol from the bloodstream to make more.\*

#### Healthy Bowel Function, Prebiotic

Glucomannan not only allows more water to remain in the stool, thereby making waste softer, larger, and easier to pass through the intestines, but it is also an excellent prebiotic.[15-17] In a placebo-controlled, randomized, parallel, double-blind, crossover trial, doses of 3 g/d and 4 g/d of glucomannan had a positive impact on intestinal habit (i.e., daily and weekly evacuations) and stool characteristics when compared to placebo. [18] Glucomannan has also been shown to reduce mouth-to-cecum transit time compared to placebo.[15] In other research, glucomannan improved defecation frequency, eased bowel movement, increased the fecal concentration of lactobacilli as well as the daily output of bifidobacteria, lactobacilli, and total bacteria. In addition, fermentation of glucomannan resulted in greater fecal acetate, propionate, and i-butyrate concentrations and lower fecal pH.\*[17]

> \*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

**IBERLEAN POWDER** 

## **Supplement Facts**

Serving Size: 6 Capsules Servings Per Container: 30

Amount Per Serving %Daily Value

Dietary Fiber 3 g (from propolmannan)(Amorphophallus konjac)(tuber)<sup>S1</sup>

†Percent Daily Values are based on a 2,000 calorie diet.

Other Ingredients: Ascorbyl palmitate, capsule (hypromellose and water), microcrystalline cellulose, and silica.

S1. Propol® is a registered trademark of Shimizu Chemical Corporation.

# Supplement Facts Serving Size: 2 Scoops (about 3.2 g) Servings Per Container: About 30 Amount Per Serving %Daily Value Dietary Fiber (from A propolmannan) (Amorphophallus konjac)(tuber)<sup>S1</sup> †Percent Daily Values are based on a 2,000 calorie diet.

Other Ingredients: None

S1. Propol® is a registered trademark of Shimizu Chemical Corporation.

#### **Directions**

Take three to six capsules once per day, or take three capsules 30 to 60 minutes before each of your two biggest meals, or use as directed by your healthcare professional.

Consult your healthcare professional prior to use. Individuals taking medication, especially hypoglycemic agents, should discuss potential interactions with their healthcare professional. Do not use if tamper seal is damaged.

#### **Directions**

Mix one to two scoops (1.6-3.2 g) in 8-12 oz of water or other nonalcoholic beverage and consume once per day, or mix one scoop as directed and consume 30 to 60 minutes before each of your two biggest meals, or use as directed by your healthcare professional.

Consult your healthcare professional prior to use. Individuals taking medication, especially hypoglycemic agents, should discuss potential interactions with their healthcare professional. Do not use if tamper seal is damaged.

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#### Formulated To Exclude

Wheat, gluten, corn, yeast, soy, animal and dairy products, fish, shellfish, peanuts, tree nuts, egg, ingredients derived from genetically modified organisms (GMOs), artificial colors, artificial sweeteners, and artificial preservatives.

\*These statements have not been evaluated by the Food and Drug Administration.
This product is not intended to diagnose, treat, cure, or prevent any disease.



REV. 04/13/22

NORTH CENTURY PHARMACY

#### Clinical Applications

- Helps Maintain a Healthy Intestinal Microecology\*
- Supports Bowel Regularity\*
- Supports Gastrointestinal-Based Immunity\*

GoodBiotic is ideal for individuals seeking a well-rounded supplement to support a healthy balance of intestinal flora, cellular health, and immune health. It features four probiotic strains, including the extensively studied HN019 strain of Bifidobacterium lactis, plus Saccharomyces boulardii (Sb), a non-pathogenic yeast, to further complement healthy gastrointestinal ecology. Gastro-resistant, vegetarian capsules provide an innovative solution for targeted delivery of sensitive ingredients to the small intestine, as they alleviate exposure to the low pH environment of the stomach. Additionally, each capsule is sealed in a nitrogen-purged blister pack to provide protection from heat, moisture, and oxygen, factors known to compromise probiotic stability.

All North Century Pharmacy Formulas Meet or Exceed cGMP Quality Standards

#### Discussion

Diversity of gut microflora is characteristic of a healthy GI microbiome and contributes to overall health and vitality by promoting optimum digestion, assimilation, gut integrity, motility, and efficient removal of toxins and wastes. Many internal and external influences, including stress, a poor diet, food sensitivities, medication, environmental factors, and certain disease conditions, can impact the microbial balance within this fine-tuned community. Their impact can allow potential colonization by pathogenic organisms and disrupt a healthy balance, which can result in adverse effects ranging from GI symptoms to impaired immune response.[1:3] Probiotics are part of the key to promoting the optimal balance of the microbiome, [4] whether they originate from dietary sources or from supplements. Probiotic yeasts, such as Saccharomyces boulardii, also play a role in gut ecology by supporting intestinal barrier function and integrity.\*

Common challenges associated with probiotic supplementation are maintaining the stability of the organisms during distribution and shelf life and, after they are swallowed, the survival of the organisms as they travel through the digestive tract to the targeted tissue. To help ensure stability, North Century Pharmacy packages GoodBiotic capsules in sealed, nitrogen-purged blister packs to serve as protection from factors proven to compromise the stability of probiotics, such as heat, moisture, and oxygen. Careful selection of organisms is another way North Century Pharmacy helps ensure stability and digestive survivability. To further support resistance to low pH and the delivery of microorganisms to the small intestines, North Century Pharmacy encapsulates the ingredients in gastro-resistant DRcaps™. These specially designed, innovative capsules help slow exposure of actives to stomach acid to promote a more targeted release.\*

HOWARU® (Bifidobacterium lactis HN019) Discovered in 1899, B lactis play a key role in the human microflora throughout a person's life. Researchers have identified strain HN019 as having excellent probiotic potential based on its ability to survive the transit through the human gastrointestinal tract, adhere to epithelial cells, and proliferate. [5] B lactis HN019 has been extensively studied, and its safety and effectiveness are well-accepted.[6,7] To assess the impact of B lactis HN019 supplementation on whole-gut transit time in adults, subjects (N = 100) were given daily doses of 17.2 billion colony-forming units (CFU), 1.8 billion CFU, or placebo for 14 days. Decreases in mean wholegut transit time over the 14-day study period were statistically significant in the high-dose group and the low-dose group, but not in the placebo group.[7] This level of dosing also supported other parameters of healthy GI function, as were self-reported by patient survey.[7] In a randomized, double-blind, placebo-controlled human dietary intervention study, 80 subjects older than 60 years who took supplementary B lactis HN019 had statistically significant increases in the beneficial organisms bifidobacteria and lactobacilli.\*(8)

Lactobacillus acidophilus (Lactobacillus acidophilus La-14) This common inhabitant of the human microbiome is also found in some traditional fermented milks (e.g., kefir) and is widely used in probiotic foods and supplements with a history of safe human consumption. The L acidophilus La-14 strain is of human origin and has been identified as a type A1 L acidophilus, showing excellent adhesion to human epithelial cell-lines.\*[9,10]

Lactobacillus plantarum (Lactobacillus plantarum Lp-115) Isolated from plant material, the L plantarum strain is abundantly present in lactic acid-fermented foods, such as olives and sauerkraut. In vitro studies have shown that L plantarum Lp-115 has excellent adhesion to epithelial cell lines.[11] In addition, L plantarum is resistant to low pH conditions and survives the presence of bile at duodenal concentrations.\*[11,12]

Bifidobacterium longum (Bifidobacterium longum BI-05) The B longum BI-05 strain is well-accepted as safe for human consumption. B longum is resistant to low pH and bile salts and is well-suited to the intestinal environment.\*[12]

Saccharomyces boulardii S boulardii might be most well-known by consumers for its role as the type of yeast used in the widely popular kombucha beverages. Extensive research in both European and American peer-reviewed journals has shown that this natural, non-pathogenic yeast has multiple mechanisms of action that support healthy gut ecology. In a 2010 systematic review and meta-analysis of 31 randomized placebo-controlled treatment arms in 27 trials (encompassing 5,029 adult study patients), S boulardii was found to be significantly efficacious in 84% of those treatment arms.[13] S boulardii was also found to be efficacious for use in children in a double-blind, randomized, placebo-controlled

Continued on next page

GOODBIOTIC

# Supplement Facts Serving Size: 1 Capsule Servings Per Container: 30

Servings Per Container: 30	Amount Per Serving	%D\
Saccharomyces boulardii	250 mg (5 Billion CFU†)	**
Proprietary Blend Lactobacillus acidophilus La-14 <sup>S1</sup> Bifidobacterium longum BI-05 <sup>S1</sup> Lactiplantibacillus plantarum Lp-115 <sup>S1</sup>	174 mg (15 Billion CFU†)	**
Bifidobacterium lactis HN019 <sup>s2</sup>	50 mg (15 Billion CFU†)	**
**Daily Value (DV) not established		

Other Ingredients: Capsule (hypromellose, gellan gum, and water), hydroxypropyl cellulose, ascorbyl palmitate, and silica.

† Colony-Forming Unit

### Howaru

S1. HOWARU® and the HOWARU® logo are trademarks or registered trademarks of IFF or its affiliates.

S2. HN019™ is a trademark of the Fonterra Group of companies used under license.

study that yielded statistically significant positive results for supporting normal gastrointestinal function in children aged 3-59 months.[14] When safety data was examined in adult subjects (n = 2,963) in a trial of patients with *Clostridium difficile* infections, the adverse reactions associated with *S boulardii* were minimal (<0.3%): thirst in five subjects and constipation in eight subjects.[13] Another study in children aged three months and older demonstrated that *S boulardii* can be used safely and effectively in this population group.\*[15]

With regard to maintaining normal GI function and transit time, research suggests that *S boulardii* secretes a protease that may assist in directly degrading bacterial toxins and stimulating antibody production against those toxins.<sup>[16-18]</sup> *S boulardii* is also believed to exert a trophic effect on intestinal mucosa and positively support the immune system.\*<sup>[14]</sup>

This probiotic yeast appears to support normal gastrointestinal flora and integrity<sup>[19,20]</sup>; promote production of intestinal enzymes and secretory IgA<sup>[21]</sup>; and support cytokine balance through its effects on IL-8, IL-6, IL-10, NF-kappaB, TNF-alpha, and PPAR-gamma, [18,22,23] Research also suggests a role for *S boulardii* in the production of health-promoting short-chain fatty acids including butyrate, which supports homeostasis of colonic flora and fuels intestinal epithelial cells among its other benefits. [24,25] The *S boulardii* used in this formula is processed by low-temperature vacuum drying for improved stability.\*

#### **Directions**

Take one capsule daily, or as directed by your healthcare professional.

Consult your healthcare professional prior to use. Individuals taking medication should discuss potential interactions with their healthcare professional.

#### Formulated To Exclude

Wheat, gluten, soy, animal and dairy products, fish, shellfish, peanuts, tree nuts, egg, sesame, ingredients derived from genetically modified organisms (GMOs), artificial colors, and artificial sweeteners.

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\*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

