

Practitioner Dietary Supplement Reference Guide – 3rd Edition

dotFIT™ CarbRepel™

Goal

To reduce a significant percentage of ingested carbohydrate calorie absorption in order to help maintain or accelerate desired weight loss during a diet and exercise program, especially in people who tend to crave or overeat carbohydrates/sugars. Additionally, the product could be used sporadically based upon days when carbohydrate intake may be unnecessarily high to help maintain or keep weight from rising. Use of this product would allow greater ingestion of carbohydrate calories but limit absorption, which might help mitigate the normal stresses and appetite struggles of weight control, including helping to maintain lean body mass (LBM) normally lost during adult weight loss when compared to a non-supplemented state.

Rationale

Refined carbohydrates including added sugars are now targets for overweight/obesity therapies because of the impact their consumption has on the regulation/cravings by our hedonic and homeostatic systems established throughout human evolution.¹ While this appetite regulation, including carbohydrate cravings (e.g. sweet tastes) was important to early human survival, it wreaks havoc in modern societies where food is not only plentiful with easy access, but extremely palatable, which often leads to unhealthy weight gain and related disease.^{2,3} The rapid decline in blood glucose after a high glycemic index* (GI) meal (high in fast digesting/refined carbohydrates) causes both homeostatic and hedonic exaggerated hunger signals,⁴ leading to cravings for more fast acting carbohydrates.⁵ In addition, the more this eating cycle continues, the less sensitive (down regulation in dopamine receptors) the brain's reward system becomes to the food signals, thus causing greater cravings and additional food to become fully satiated or satisfied.⁶ This latter problem describes the typical "sweet tooth" feelings even after a full meal despite not being truly "hungry."⁴ For the many people that find themselves in this eating conundrum, CarbRepel may assist by allowing reasonable carbohydrate intake to help satisfy cravings while preventing a portion of it from being absorbed, thus reducing calorie intake.

Phaseolus vulgaris (†† Phase 2®)

The common white bean, *Phaseolus vulgaris*, produces an alpha-amylase enzyme inhibitor (the enzyme that breaks down carbohydrates and allows them to be absorbed into your body⁷), which has been characterized and tested in numerous clinical studies.⁸ A specific and proprietary product named Phase 2® Carb Controller (Pharmachem Laboratories, Kearny, NJ) has demonstrated the ability to enhance weight loss when compared to placebo with doses of 500 to 3,000 mg per day, in either a single dose or in divided doses by blocking the action of alpha amylase⁸ and produce superior results when compared with other starch/carbohydrate blockers with anti-amylase activity.⁹ In one study subjects taking 445 mg of Phase 2 before one high carbohydrate meal daily within a 2,000 to 2,200 calorie diet had significantly greater reduction of body weight, (6.6 lbs versus 0.8 lbs with placebo) BMI, fat mass, adipose tissue thickness, and waist/hip/thigh circumferences while maintaining lean body mass compared to subjects receiving placebo.¹⁰ In the same vein, a four week trial with subjects ingesting 1,000 mg of Phase 2 twice daily before meals in combination with diet, exercise and behavioral counseling, demonstrated that only the participants consuming the most carbohydrates lost significantly more weight than placebo users (8.7 lbs versus 1.7 lbs, respectively).¹¹ Other clinical research found taking 1,000 mg of Phase 2 standardized to a minimum of 3,000 AAIU (alpha-amylase inhibiting units), three times daily before meals for 60 days modestly reduces body weight and waist circumference compared to placebo in overweight and obese individuals.¹² Patients treated with Phase 2 had an average weight loss of 4.2 lbs and an average reduction in waist circumference of 1.9 cm compared with 0.8 lbs and 0.4 cm lost by patients on placebo. Both groups were not assigned to a diet or exercise program.¹² In a randomized placebo controlled study, the safety and efficacy of *Phaseolus vulgaris* (Phase 2), on weight management in two phases was evaluated. The weight loss (WL) phase (~500 calorie daily deficit) was conducted over 12 weeks and the weight maintenance (WM) phase lasted

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24 weeks with no diet restrictions, so it mimicked free living. The dosage was 1,000 mg taken three times daily before meals for both studies. At the end of the WL study, the Phaseolus vulgaris (PV) group lost a mean of 6.4 lbs in body weight compared with 2.0 lbs in the placebo group. During the WM phase, 36 out of 49 subjects (73.5%) were able to maintain their weight, even without dietary restrictions. No serious or related adverse events were reported over the combined period of 36 weeks. Participants during the WL phase reported no hunger differences during diet compared to normal living. The conclusions were that PV/Phase 2 is safe and effective for weight loss and maintenance.¹³

*Glycemic Index (GI)

High glycemic carbohydrates (refined grains/sugars, etc.) break down and enter the body faster than lower glycemic foods (fibrous, whole grains, etc.) and depending on what foods accompany the carbohydrate (CHO) during a meal, high GI CHO consumption can negatively affect hunger/cravings, satiety, blood sugar and ultimately health.^{2,3,8} The glycemic index (GI) is defined as the incremental area under the blood glucose curve after ingestion of a test food, expressed as a percentage of the corresponding area following an equivalent load of a reference carbohydrate, either glucose or white (wheat) bread.¹⁴ Low Glycemic diets have been associated with healthier outcomes,^{2,3,15} including improved blood sugar control and insulin sensitivity,¹⁶ and a longer feeling of fullness.¹⁷ Phase 2 was tested for its ability to lower the glycemic index (GI) of ingested carbohydrate. Using white bread as the test carbohydrate, Phase 2 was found to significantly reduce its GI thus demonstrating its ability to improve the GI of meals that include simple starches/carbohydrates.^{8,18} Clinical studies also show that Phase 2 has the ability to reduce the post-prandial spike in blood glucose levels.⁸

Extrapolated from all current data, Phase 2 appears to be safe and effective for weight/BMI reduction, attenuating loss of LBM and maintenance of weight loss when 1,000 mg is ingested before a meal containing typical "Western diet" amounts (>30%) of carbohydrates. With weight loss prescription drugs being deemed to have too many negative side effects (including some being pulled off the market¹⁹) with minimal results,²⁰ there is high interest in products like Phase 2 and other natural sources for assisting in weight management.²¹

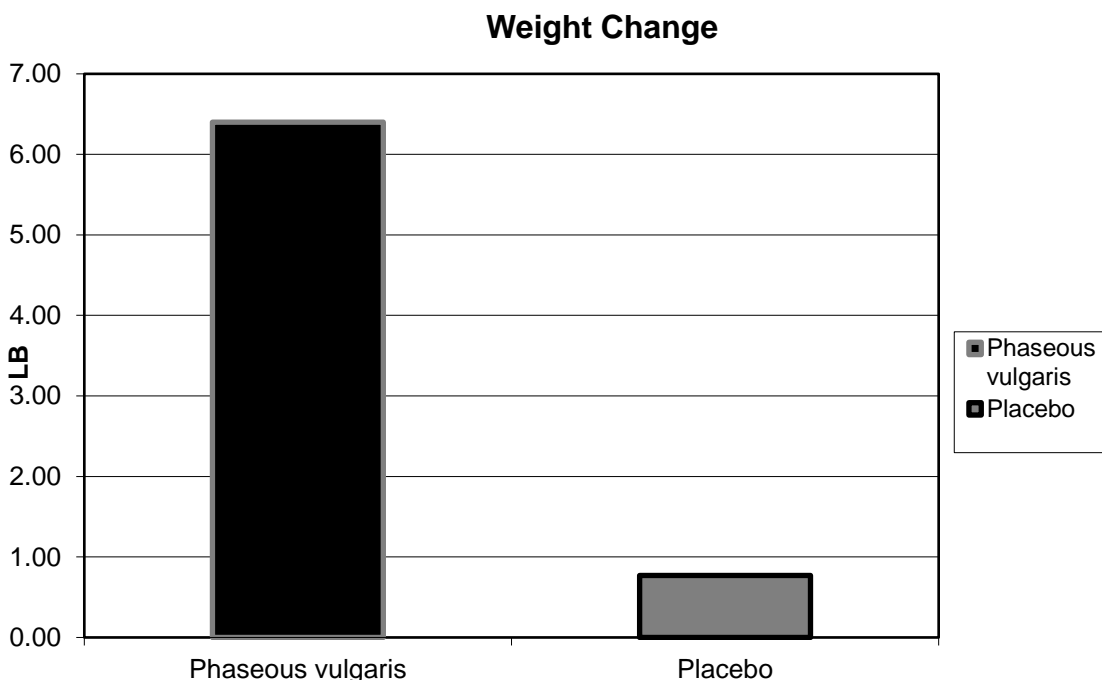


Figure 1 - Subjects consumed a 2,000-2,200 calorie carbohydrate-rich diet. The Phase 2 group experienced ~700% greater weight loss compared to the placebo.¹⁰

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Cofactors

Citrus Pectin (CP) is a fiber found in many fruits and only used in this product as a natural filler to help in the delivery of the active ingredient *Phaseolus vulgaris* (Phase 2). CP is administered in doses greater than 5 g during a meal has been demonstrated to slow gastric emptying.²² In other words, it helps keep food in the stomach longer. CP used in appropriate amounts may assist in controlling appetite by allowing the user to feel fuller sooner and longer thus potentially delaying or reducing the next meal.^{23,24,25}

Pomegranate leaf extract (PLE) is a natural constituent of *Punica granatim* leaves and like CP, is only used in this product as a natural filler to help in the delivery of the active ingredient *Phaseolus vulgaris* (Phase 2). PLE in doses >700 mg are often used for the plant's antioxidant, anti-inflammatory^{26,27} and potential blood flow augmentation properties.²⁸

†† The trademark Phase 2 Starch Neutralizer® is being used under license.

Typical Use

- Non-stimulant fat-loss and appetite aid for those who tend to enjoy or overeat carbohydrates
- Anyone seeking to enhance body-fat reduction without affecting the central nervous system
- Discontinue after reaching fat loss goal or until lifestyle helps maintain desired progress
- Can be used alone or as part of the dotFIT 90 Day Weight Loss Solution (a.k.a. LeanPak 90)
- Take two (2) tablets, twice daily, 30 minutes before your largest carbohydrate-containing meals or snacks with at least 8 ounces of appropriate fluid

Precautions

CarbRepel™ is generally considered a safe fat-loss aid when used appropriately. Based on *Phaseolus vulgaris*'s potential ability to mitigate "blood sugar spikes" and overall glucose effect, persons using diabetes medication should monitor blood glucose closely.²⁹

Contraindications

The compounds in CarbRepel™ are contraindicated in pregnancy and lactation because of a lack of data for this population.

Adverse Reactions

- **Phaseolus vulgaris** used appropriately seems to be safe with few to no side effects when used for two to eight months.^{12,13,30,31} In large doses Phase 2 may cause gastrointestinal distress in susceptible users.³²
- **Citrus Pectin** is present at 750 mg per dose in this product. In large doses (20g) CP used in foods can cause gastrointestinal side effects.³³ Pectin has Generally Regarded as Safe (GRAS) status in the United States.³⁴
- **Pomegranate leaf extract** in this product dose has no known adverse effect.

Upper Limit/Toxicity

There are no established upper limits for the compounds found in CarbRepel™

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Summary

Purpose

- The purpose of this product is to reduce ingested calories from carbohydrate by inhibiting their absorption in order to ease and accelerate body-fat reduction
- A non-stimulant fat loss aid for those that tend to enjoy, crave or overeat carbohydrates

Unique Features

- The all natural ingredient Phase 2[®] is the first nutritional ingredient that has been clinically and scientifically proven to neutralize starch
- The FDA has accepted the following claims based on 16 clinical investigations:
 - “May assist in weight control when used in conjunction with a sensible diet and exercise program”
 - “May reduce the enzymatic digestion of dietary starches”
- Can be used alone or as part of the dotFIT 90 Day Weight Loss Solution (aka LeanPak90)
- Manufactured in a regularly inspected NSF certified facility, in compliance with Good Manufacturing Practices

Supplement Facts

Supplement Facts	
Serving Size: 2 Tablets	
Servings Per Container: 60	
Amount Per Serving	% DV
Phase 2 Starch Neutralizer ^{®†}	750mg *
White Kidney Bean Extract (Phaseolus vulgaris)	
Citrus Pectin	375 mg *
Pomegranate Fruit Extract	137.5 mg *
(Total Polyphenols 110 mg, Ellagic Acid 55 mg)	
*Daily Value not established.	

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