

a unique, patented form of chitin shown to help maintain healthy cholesterol levels

binds to cholesterol in the gut preventing its absorption

does not interfere with absorption of essential nutrients

safe and well-tolerated by most individuals

clinically proven

Cardiovascular disease is the most prevalent disease in the Western world, resulting in millions of deaths and billions of dollars spent on treatment. High serum total cholesterol and/or the combination of high LDL cholesterol and low HDL cholesterol are confirmed independent risk factors for cardiovascular disease. In an effort to reduce disease risk, many health-care practitioners suggest dietary changes and prescribe substances to improve these blood lipid levels. Some of the methods employed, such as HMG CoA reductaseinhibiting (statin) drugs, are not well-tolerated by some patients, while other individuals are opposed to taking these drugs. In addition, some individuals do not reach target serum cholesterol and LDL levels with statin drugs alone.

Most of the cholesterol in the bloodstream is produced in the liver, with a smaller amount derived from the diet. Addressing both hepatic production and gastrointestinal absorption of cholesterol can be of benefit in maintaining normal cholesterol levels.

Pharmacol-40<sup>™</sup>, a patented product by Thorne

#### The Science Behind Pharmacol-40<sup>™</sup>

**Pharmacol-40** is a specific low-molecular weight polysaccharide derived from the enzymatic hydrolysis of chitin, a polyglucosamine substance found in crab and shrimp shells.

**Pharmacol-40** is a large molecule that resists digestion and therefore is not absorbed into the bloodstream – instead, it remains in the gastrointestinal tract where it acts like a magnet, attaching to cholesterol from the diet. This forms an insoluble complex, which is not absorbed. **Pharmacol-40** also attaches to cholesterol that has been produced in the liver and secreted in the bile, preventing reabsorption in the intestines.

In a placebo-controlled, multicenter, clinical trial, 105 patients with mild-to-moderate hypercholesterolemia were randomized to receive HEP-40 (the active ingredient in **Pharmacol-40**) at varying doses or placebo, and evaluated at baseline, four, eight, and 12 weeks. Of the 105 eligible patients, 17 (16%) were randomized to 400 mg HEP-40 three times daily, 24 (23%) to 800 mg HEP-40 twice daily, 23 (22%) to 800 mg HEP-40 three times daily, 22 (21%) to 2,400 mg HEP-40 once daily, and 19 (18%) to the placebo group. Ultimately, 86 (82%) received HEP-40 treatment. Table 1 summarizes the percent change for all lipid profile parameters in HEP-40 treated patients versus placebo. With respect to the primary outcome measure, the percent change in LDL cholesterol after four weeks of study treatment, the results showed a significant treatment effect (p=0.040). The highest difference in percent change in LDL cholesterol from the placebo group was observed for the 2,400-mg once daily group (-16.9%; p=0.002).

This study showed **Pharmacol-40** low-molecular weight chitosan is efficacious in reducing serum LDL cholesterol and is safe and well-tolerated. A dose-response relationship was demonstrated with higher and more concentrated doses producing greater reductions in LDL cholesterol.

Since **Pharmacol-40** binds to cholesterol in the gut, the researchers assessed if fat-soluble vitamin absorption might be inhibited. Serum 25(OH) vitamin D levels were tested in a random sample of 91 patients and 22 in the placebo group at baseline and at 12 weeks. No significant difference was seen between groups.

Pharmacol-40 absorbs water in the intestines and acts similar to dietary fiber. It is safe and well tolerated by most individuals. Pharmacol-40 does not inhibit the absorption of essential nutrients, such as fat-soluble vitamins.

		HEP-40 group versus Placebo			
		Mean (SE) Difference in Percent Change (P Value)			
Week	Lipid Parameter	HEP-40 400 mg TID	HEP-40 800 mg BID	HEP-40 800 mg TID	HEP-40 2400 mg QD
	LDL-C	-11.1 (3.9)	- 8.7 (5.2)	-9.7 (5.2)	-16.9 (5.2)
4	(mg/dL)	(0.054)	(0.101)	(0.065)	(0.002)
	TC	-8.4 (3.8)	-10.4 (3.5)	-5.1 (3.5)	-12.3 (3.6)
	(mg/dL)	(0.032)	(0.004)	(0.141)	(0.001)
	TG	-6.5 (19.1)	-9.5 (17.5)	-10.3 (17.3)	3.3 (17.8)
	(mg/dL)	(0.733)	(0.587)	(0.553)	(0.853)
	HDL-C	-4.6 (6.1)	-5.4 (5.6)	-3.0 (5.5)	-8.5 (5.7)
	(mg/dL)	(0.455)	(0.338)	(0.588)	(0.140)
8	LDL-C	-15.1 (5.4)	-15.1 (4.7)	-13.5 (4.8)	-17.7 (4.9)
	(mg/dL)	(0.006)	(0.002)	(0.006)	(0.001)
	TC	-15.1 (4.2)	-13.0 (3.8)	-9.9 (3.8)	-14.0 (3.9)
	(mg/dL)	(0.001)	(0.001)	(0.012)	(0.001)
	TG	-16.3 (18.0)	-29.9 (15.9)	-14.9 (16.3)	-5.3 (16.6)
	(mg/dL)	(0.367)	(0.064)	(0.360)	(0.751)
	HDL-C	-7.5 (5.4)	1.7 (4.8)	0.3 (4.9)	-4.1 (5.0)
	(mg/dL)	(0.171)	(0.730)	(0.956)	(0.412)
	LDL-C	-13.3 (6.3)	-8.4 (5.5)	-11.0 (5.6)	-10.9 (5.6)
12	(mg/dL)	(0.38)	(0.126)	(0.050)	(0.055)
	TC	-6.2 (3.6)	-7.9 (3.2)	-4.7 (3.3)	-7.2 (3.3)
	(mg/dL)	(0.090)	(0.014)	(0.151)	(0.030)
	TG	-8.9 (16.0)	-27.2 (14.1)	-15.7 (14.0)	-21.4 (14.6)
	(mg/dL)	(0.579)	(0.057)	(0.280)	(0.146)
	HDL-C	3.3 (4.7)	6.7 (4.1)	1.3 (4.3)	4.9 (4.3)
	(mg/dL)	(0.489)	(0.111)	(0.758)	(0.250)

Table 1. Percent Change in Lipid Parameters by Treatment Group

TC = Total Cholesterol; TG = Triglycerides; P value based on Linear Regression Analysis and Post-Hoc Tukey's test for Least Significant Difference (LSD)

#### How to Use Pharmacol-40<sup>™</sup>

Dosage Recommendation: Three 800-mg capsules taken once daily with the evening meal.

Side Effects and Contraindications: Occasionally, individuals taking the ingredient in Pharmacol-40 have experienced gastrointestinal discomfort. If you are taking lipid-lowering medications, consult your health-care practitioner before taking this product.

Pregnancy: A woman who is pregnant, or might become pregnant, should consult a health-care practitioner before using this product.

## **Supplement Facts**

Serving Size: Three Capsules

Three Capsules Contain:		% DV
Chitosan-40kDa**	2,400 mg.	*

Other Ingredients: Hypromellose (derived from cellulose) capsule. MagnesiumCitrateLaurate, Leucine, Silicon Dioxide. Contains ingredient derived from shellfish (crab, shrimp).

The active ingredient in Pharmacol-40 is a specific low molecular weight Chitosan (Chitosan-40kDa\*\*) produced by a patented enzymatic hydrolysis process.

# Pharmacol-40<sup>™</sup>

90 Vegetarian Capsules Code: SP651 Dosage: 3 capsules once daily with evening meal



simple and convenient dosing for great patient compliance – three capsules once daily with evening meal!



### clinically proven Pharmacol-40

a unique, patented product shown in clinical trials to help maintain healthy cholesterol levels

for more information go to www.pharmacol-40.com



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