Can Nutraceuticals Lower Your Cholesterol?

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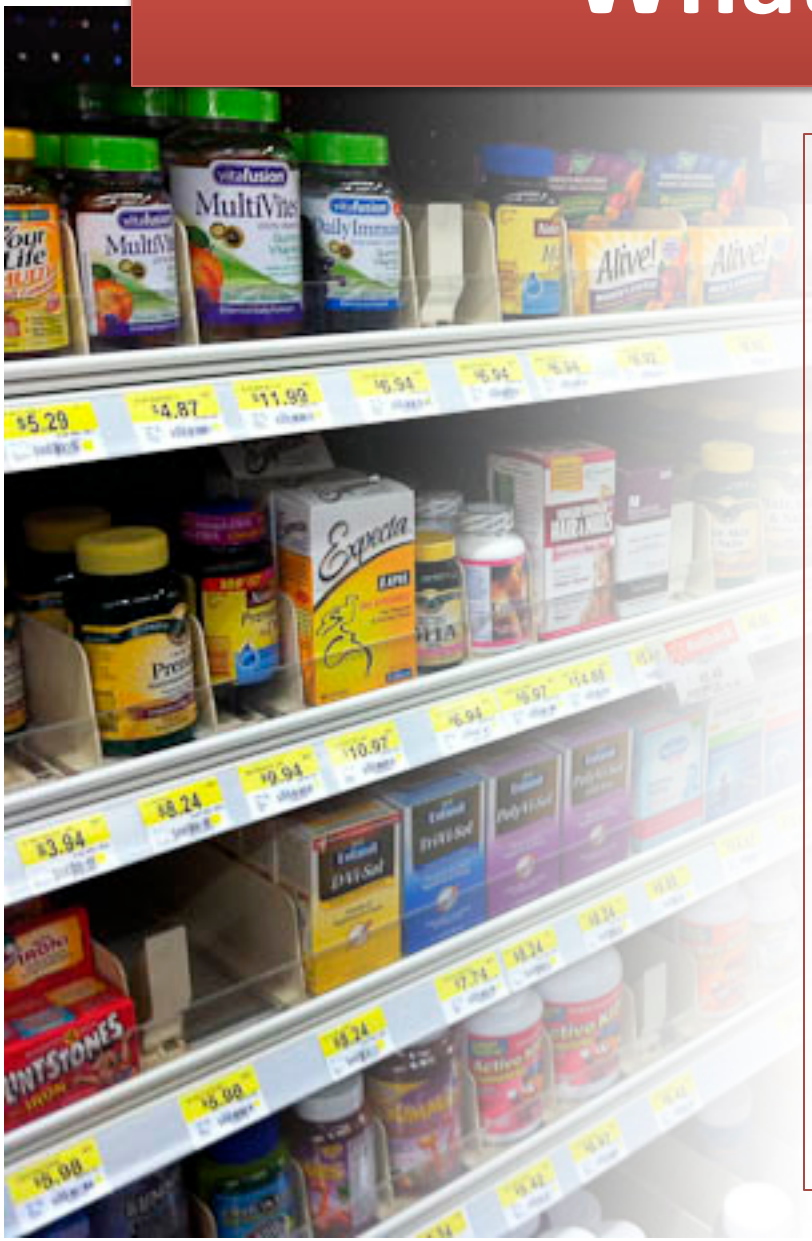
Are over-the-counter supplements,
sold as cholesterol lowering agents,
such as Red Yeast Rice,
Plant Sterols,
Policosanol,
or Guggulipids

useful or useless?

Sources for Health Claims

- Poorly conducted studies published in industry-supported magazines or non-peer reviewed journals
- Review articles from third world countries,
- No source other than an Internet article.

What Patients Do



- $75 billion/year in nutritional supplements
- Walmart website lists 65 nutraceuticals associated with cholesterol health

Patients Want To Take Control

But many, if not most, of these products won't do much to help and some are likely downright harmful.

We Will Examine

1. Red Yeast Rice (RYR)
2. Sterols
3. Guggul (Guggulipids)
4. Policosanol

RED YEAST RICE (RYR)

- Monacolin K (Monascus purpureos)
- Historically it is the active ingredient
- Identical to synthetically-produced Lovastatin

Product Reformulated

- FDA determined RYR did not conform with 1994 Diet Supplement and Health Education Act (DSHEA)
  - Lovastatin approved **before** RYR entered market
- RYR sold in the US had to be reformulated
  - Shouldn't contain Monocolin K
- We can't be sure what red yeast rice compounds contain today

Xuezhikang (XZK) Variation

- 2008-published study:
  - Double-blind, placebo study in Chinese hospitals
  - 4,870 patients with heart attack within the past 5 years
- Striking findings:
  - 45% reduction of risk of major coronary events
  - Statistically significant reductions in CV and total mortality

However…

- National Lipid Association told physicians and patients: beware, product composition unknown
  - XZK ingredient: purified extract of Chinese RYR with multiple components
- Not sold in the USA
- No FDA approval
- Not identical to other US-sold products
- May be obtained in the US—illegally
- Full extent of lipid- lowering benefits –if any– is unknown

RYR Products in the US

- We don't really know what's in them
- May also contain citrinin (nephrotoxic in animals and shown to be mutagenic in low concentrations when in food colorant)
- Also found to contain monocolin K, plant sterols, CoQ-10, niacin, etc.

A 2010-published study testing 12 RYR products said to contain 600 mg of RYR found all contained Monacolin K between .31 and 11.5 milligrams per capsule. 20.5 mg of Monocoling K/day = starting dose of lovastatin

FDA Oversight

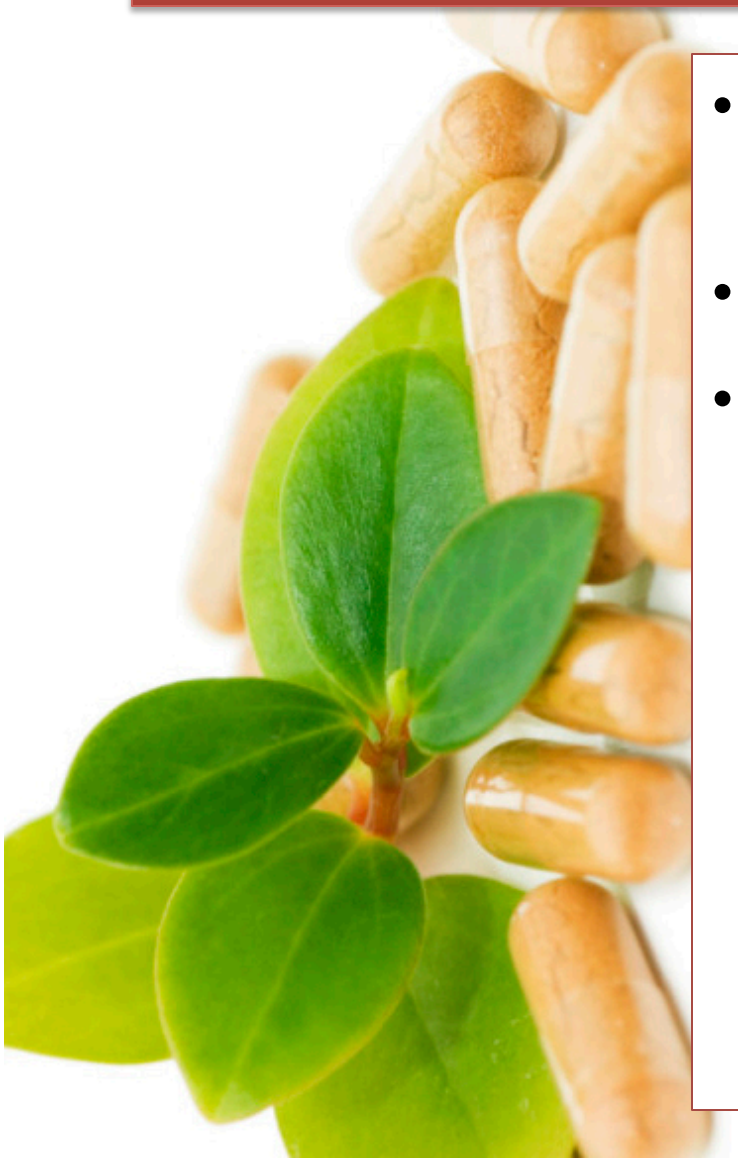
2013-published study from the Journal of Clinical Lipidology assessed FDA oversight of 101 products containing red yeast rice and reviewed the labeled content of available products:

- FDA had no information on the number of manufacturers
- No information on compliance with Current Good Manufacturing Processes (CGMP)
- No product could be confirmed as passing any independent laboratory verification testing.

Bottom Line:

- Efficacy has not been proven for any indication
- Patients should NOT take any red yeast rice supplement if they are already taking a medicine for cholesterol management
  - Potential adverse effects
- RYR should not be substituted for statins:
  - Active ingredients unknown
  - No information on compliance with Current Good Manufacturing Processes (CGMP)

STEROLS



- Waxy, insoluble substances crucial to cell membranes
- Best known: cholesterol
- Non-cholesterol sterols: plant sterols or phytosterols
  - Over 40 recognized non-cholesterol sterols: plants, yeasts, fungi, and shellfish
  - Present in the human diet
  - In Western diets in amounts equal to that of cholesterol (150-300 mg daily)

STEROLS

- Sitosterol is best known and most abundant
- Normal human absorption of sitosterol is minimal and blood levels are extremely low (< 1mg/dl)

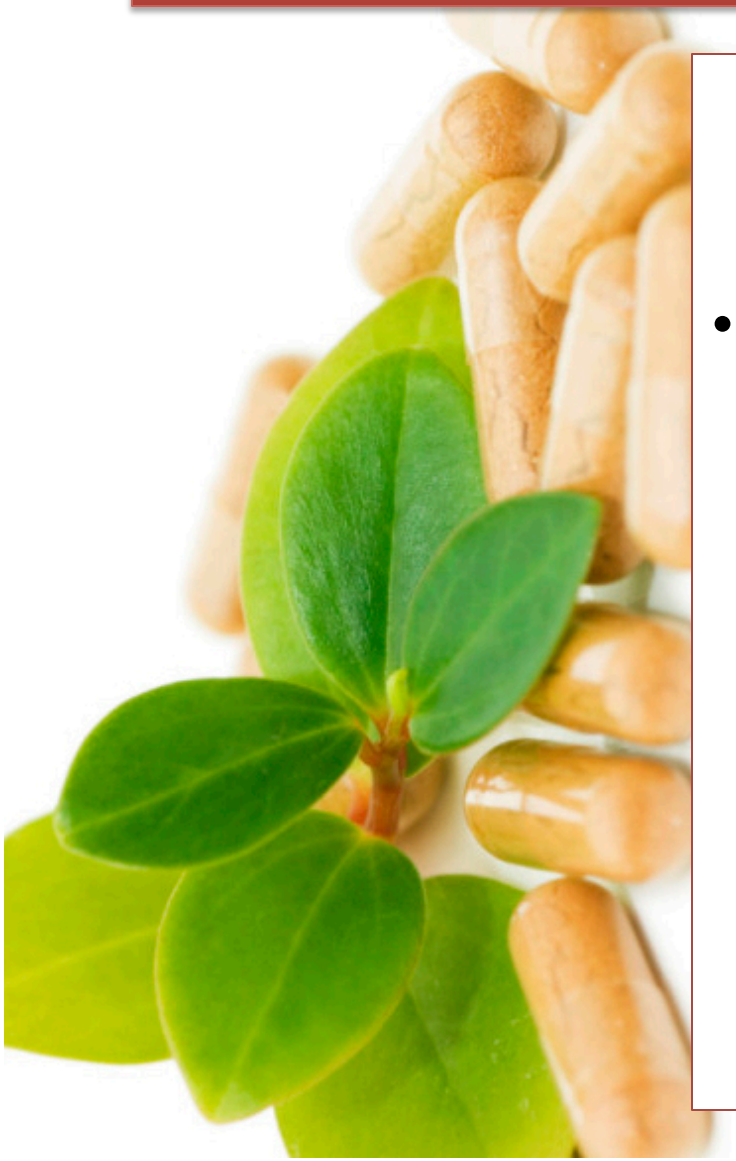
Unlike cholesterol, no phytosterol has any human physiologic function

Benefits

For over 50 years, plant sterols have been used therapeutically to reduce cholesterol levels. Numerous double blind studies show LDL cholesterol lowering of 10-14%.

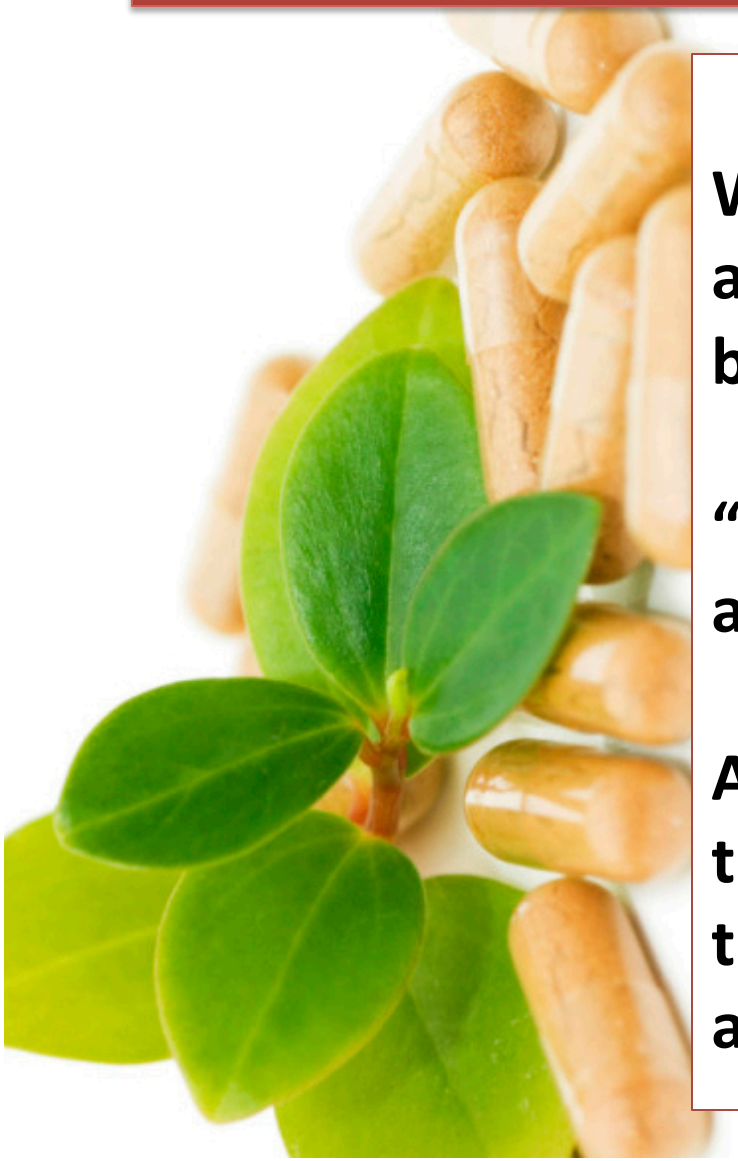
Phytosterols recommended by NCEP ATP III as an adjunct to lifestyle changes to help lower total and LDL cholesterol levels.

However…



- Food industry adding plant sterols to many foods to market them as "healthy" and "good for you”
  - Added to foods, vitamins, supplements, baby aspirin

The Danger



When any sterol enters the arterial wall and is ingested by a macrophage, it becomes a sterol-laden foam cell.

“Foams cells” = hallmark of atherosclerosis.

Any sterol in the human blood stream transported by a lipoprotein particle to the arterial wall can become an atherosclerotic plaque.

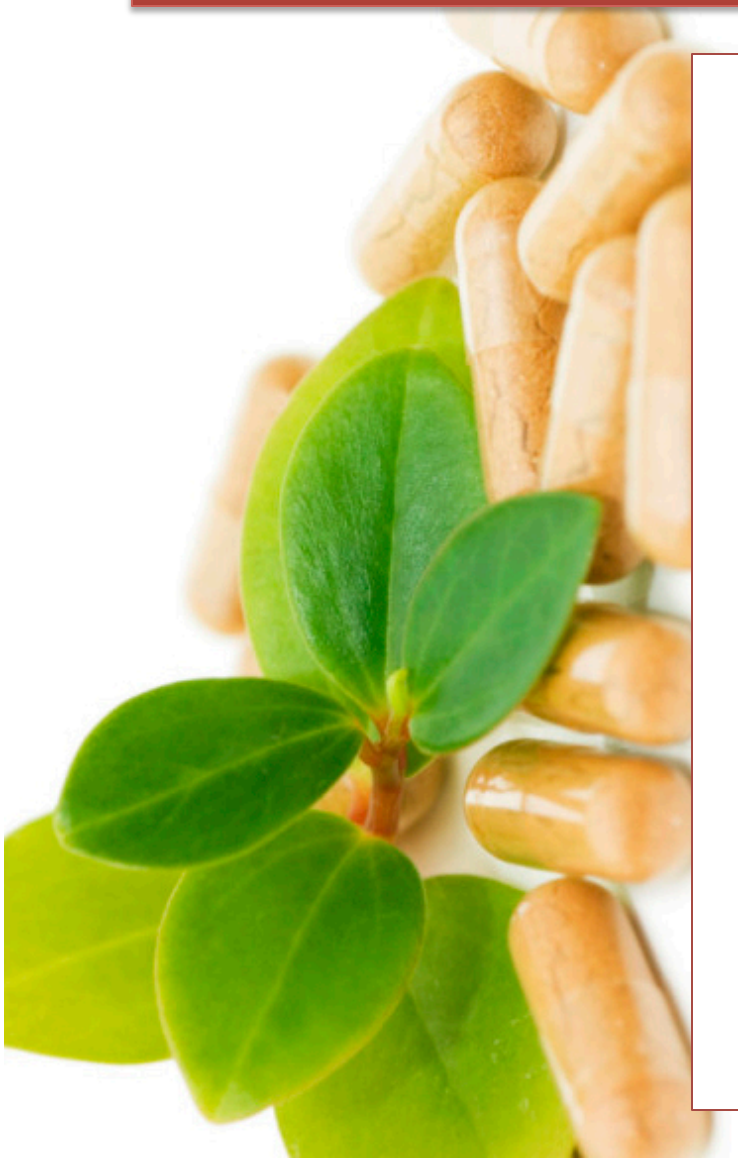
The Danger

No data from randomized human trials

- Risky for some. Normal absorbtion ~50%
  - Some absorb 60 to 80% of both cholesterol and non-cholesterol sterols
- Higher incidence of non-cholesterol sterols among menopausal women, strong family history of premature atherosclerosis, and <u>patients on statins</u>

You can have clogged arteries even if you are a vegan!

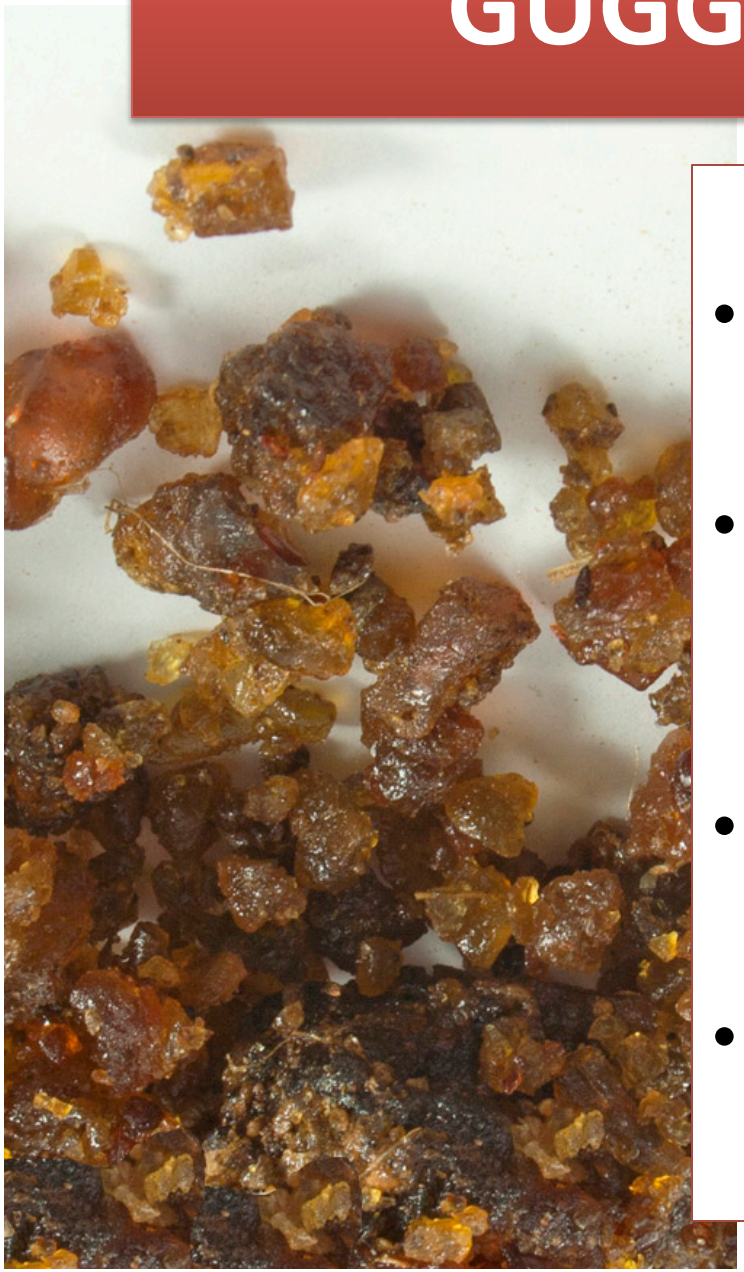
Bottom Line



Using phytosterols as a food additive is **not** a good idea.

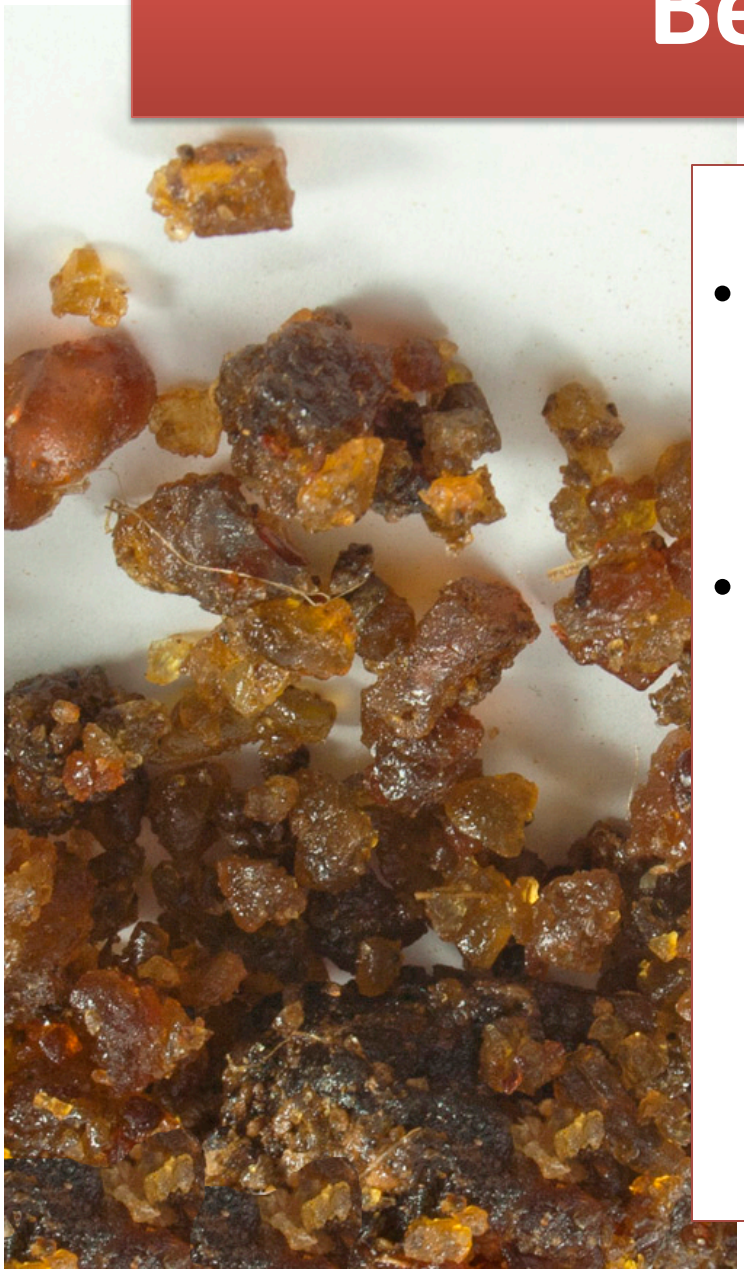
Heightens risks of athero-sclerosis for a vulnerable segment of the population.

GUGGUL (Guggulipids)



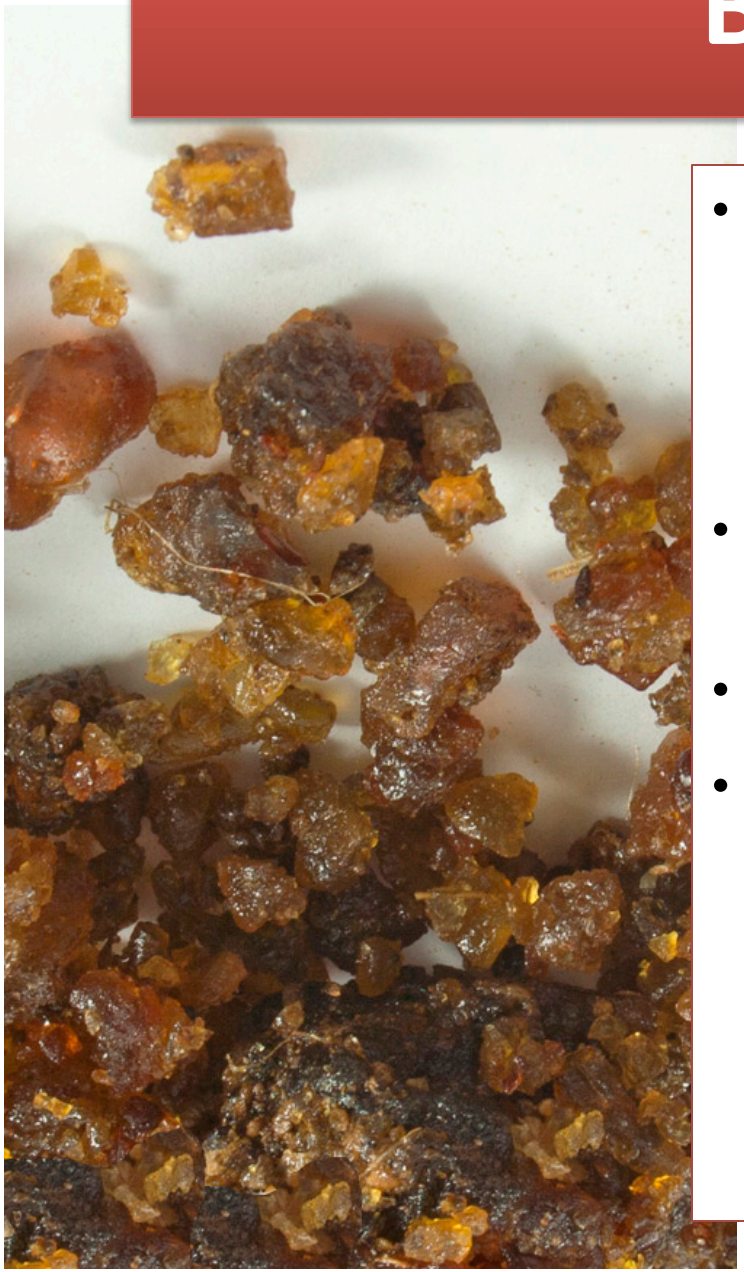
- Found in the arid regions of India and Pakistan
- Believed to be the active ingredients in the resin of the Commiphora Mukul "Guggul" tree
- Marketed in the US under the name "Guggulipids" as dietary supplement
- Promoted to control cholesterol

Benefit Claims



- One placebo-controlled trial found 12% lower LDL cholesterol
  - Approved for use in India
- US 8-week, double blind randomized, placebo-controlled trial:
  - Guggulipids did **not** lower LDL cholesterol
  - Increased LDL in most patients
  - Higher hypersensitivity rashes (9% of the participants).

Bottom Line



- Some patients responded well in both Indian and Western studies
  - Does Indian population differ genetically or environmentally from Caucasian population?
- Active ingredient in the resin of Commiphora Mukul tree in India/Pakistan
- Gum Resin used in Indian Medicine for 2000 years
- Only one US double-blind randomized trial
  - Hypersensitivity rashes
  - Higher LDL-C in majority of patients

POLICOSANOL

A mixture of long-chain primary aliphatic alcohols isolated from sugarcane wax.

Also be derived from wheat germ, rice bran and beeswax.

The most widely available product comes from Cuba and is sold as a lipid lowering product in over 40 countries.

Benefit Claims & Counterclaims

- Early studies conducted by a single Cuban research group showed promise
- Recent publication of negative studies outside of Cuba
- Recent placebo-controlled trials failed to find any significant lipid-altering effects.
- 2006 US/German trials found no effect on LDL-C at 10-80 mg/day

Bottom Line

Policosanol cannot be recommended for treatment of hyperlipidemia

CONCLUSIONS

Caveat Emptor - Let the buyer beware

- Some over-the-counter supplements **may** help in *some* patients, under *some* conditions
- But may conflict with medications
- Sometimes outright harmful
- Always check with physician **before** using

THANK YOU!

Questions

&

Answers