

# NIACIN SR™



## CLINICAL APPLICATIONS

- Support for Optimizing Serum Lipid Levels including: HDL, LDL, Lipo(a), Triglycerides

*Nearly every panel of experts, including the National Cholesterol Education Panel (NCEP) considers niacin "first-line therapy" for improving blood lipids related to cardiovascular health. Niacin is the ONLY therapy that consistently improves the ENTIRE lipid profile. 3rd Opinion Inc®'s Sustained-Release Niacin, with its proprietary wax-coated technology, not only supports healthy lipid levels just as well as the instant-release forms; it also dramatically reduces the flushing effect. This means potentially more people can realize its benefits.*

**Niacin SR™ is manufactured in a Federal Drug Registered and State Board Pharmacy cGMP laboratory**

## DISCUSSION

The benefits of niacin, vitamin B3 were introduced in the June, 1956 issue of Mayo Clinic Proceedings.<sup>1</sup> More than 20 years later the Framingham Heart Study indicated niacin reduced triglycerides and LDL, and increased HDL. Ten years later, the Framingham Heart Study labeled niacin, "Front Line" treatment.<sup>2</sup> In 1988, just one year later, the NCEP designated niacin, "First Line Therapy" in the treatment of hyperlipidemias.<sup>3</sup>

There are several theories behind niacin's mode of action. 1) It inhibits the formation of VLDL in the liver. VLDL is converted to LDL and triglycerides. 2) Niacin reduces the non-esterified or free fatty acids and triglycerides by inhibiting the breakdown of fat in tissues. 3) Last, niacin stimulates bile flow (and when used with resins) may suppress cholesterol synthesis. It does not change the composition of the bile.<sup>4</sup>

From the late 1970's through the turn of the century dozens of clinical trials have taken place at leading universities and institutions. Some trials compared niacin to other lipid management therapies such as resins, fibrates, or neomycin. Others studied the vitamin in combination with statin drugs or as solo treatments. The individual study periods were from 4 weeks up to 5 years duration. Study after study consistently demonstrated that niacin decreases triglycerides and LDL, and increases HDL. Niacin is the only therapy that consistently improves the entire lipid profile; and the only treatment to lower Lp(a).<sup>5,6</sup>

So, why is niacin not used more widely? The two common concerns are (harmless) cutaneous flushing that may last from 10-15 minutes (rarely, but possibly up to 2 hours); and increases in liver enzymes; signaling potential hepatotoxicity. The first concern can be dramatically reduced with sustained-released niacin such as Niacin SR™. The second concern came about as the result of McKenney's study published in 1994 in the JAMA in which subjects, regardless of the decline in their lipids with lower doses, continued to receive up to 3000 mg/day of niacin.<sup>7</sup> McKenney retracted his earlier warnings about the harmful effects of niacin in April, 2004 and publicly supported its unique benefits.<sup>8</sup>

### Special Considerations & Potential Side-Effects

Liver enzymes may increase when initiating niacin therapy, especially in amounts greater than 1000 mg/day. Therefore, enzymes should be monitored by a knowledgeable health care practitioner. The levels generally do not enter an unhealthy range. It is prudent to perform a liver profile every 2-3 months for the first year; then annually if levels have been healthy. Enzyme levels return to normal promptly after cessation of niacin.<sup>9,13</sup>

Uric acid levels, especially in patients with a history of gout should also be monitored. The combination of Niacin SR™ with aspirin increases the likelihood of hyperuricemia. Uric acid levels can be managed with folic acid such as found in 3rd Opinion Inc®'s Methyl Protect™ and/or supplementing with a minimum of 500 mg/day of vitamin C.



Blood levels of homocysteine should likewise be monitored. Healthy levels can be supported with vitamins B2, B12, folate, and trimethylglycine at dosages available in Methyl Protect™ and TMG™, if extra trimethylglycine is required.<sup>11</sup>

Although poor glycemic control in Type 2 diabetes has been demonstrated with the use of crystalline nicotinic acid, studies using 1000–2000 mg of sustained-release niacin suggested these doses have minimal impact upon insulin sensitivity.<sup>12</sup>

Adherence to the regimen of this special wax-coated form of niacin ranged from 88-97% throughout four human clinical trials that tested it. Flushing, itching, tingling and upper gastrointestinal side-effects were minimal, but increased when dosing went to 2000 mg/d.<sup>13</sup>

### Supplement Facts

Serving Size: 1 Tablet  
Servings Per Container: 120

|                         | Amount | %Daily Value |
|-------------------------|--------|--------------|
| Niacin (nicotinic acid) | 500 mg | 2500%        |

**Other Ingredients:** Vegetable Stearine, Carnauba Wax, Magnesium Stearate and Silica

### DOSING:

When moving from plain niacin to Niacin SR™, the dose should be cut in half. Niacin SR™ has a highly specific and consistent nicotinic acid release pattern designed to boost HDL. Due to the wax-coat technology do not cut or break the tablet. (Store in a cool, dry place.) Maintaining consistency of dosing may reduce flushing. Other flush-minimizing strategies include: taking an aspirin approximately 1 hour before Niacin SR™, (under practitioner supervision), avoid taking on empty stomach or with hot beverage, take at bedtime.<sup>13,14</sup>

Cost-effective, convenient Niacin SR™ may be used alone or to enhance other pharmaceutical therapies for hyperlipidemia.

### REFERENCES

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Additional references available upon request .

### CAUTION: Avoid during pregnancy and lactation.

Note: Niacin SR™ should not be confused with “No-Flush” niacin which is inositol hexanicotinate (IHN), a supplement that does not contain any free niacin and has not been shown to be efficacious in hyperlipidemias

\*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.

