


Dear Clinician,

Thank you for your interest in Endur-acin® and its use in published clinical studies for the treatment of dyslipidemias. Endur-acin® is a wax-matrix, sustained release formulation of nicotinic acid (NA) produced by Innovite Inc, a custom manufacturer of bulk nutritional supplements in Tigard, OR since 1976. Endurance Products Company is the exclusive marketing affiliate of Innovite.

Currently, fourteen investigator-initiated studies of Innovite’s wax-matrix nicain have been published. Four studies examine tablet content, dissolution, bioavailability, and peak plasma levels. The ten remaining studies report the safety and efficacy on lipid parameters and blood chemistries.

Pharmacokinetics

Figge HL, et al compared the bioavailability of wax-matrix NA to Nicobid® (Roher) by measuring 24 hr urinary recovery and found greater bioavailability for wax-matrix NA.1 Meyers CD, et al analyzed free nicotinic acid content of OTC niacin preparations and found variability between preparations, but that Endur-acin® was consistent with free NA content. Of significance, the authors noted that use of OTC sustained-release preparations should be limited to products that have been objectively shown to be safe and effective – of which Endur-acin® was one of only two cited profiles of seven non-prescription NA preparations to a published reference dissolution algorithm. This analysis confirms the intermediate release profile of Endur-acin®, showing a serum peak at about 6 hours.

Pharmacodynamics

The ten remaining studies are clinical efficacy and tolerability studies. Alderman JD et al conducted an uncontrolled trial in 101 patients with CAD and TC/HDL ratios >4. At 12 months the group achieved a 31% increase in HDL and a 32% decrease in TC/HDL, with only 4% dropout. Because the investigators used both immediate release (Squibb) and wax-matrix NA, the pooled results cannot be attributed to either agent alone.3 Keenan JM et al examined 201 patients with elevated LDL utilizing four dosages of wax-matrix NA (Endur-acin®) compared to placebo and diet treated controls. The groups given 2000 and 1500 mg demonstrated 26% and 19.3% reductions in LDL, and an 18.4% and 13.3% reduction in TC/HDL ratio. Tolerance was good with only 3.4% dropping out due to niacin side effects. The authors conclude “the improved side effect profile and low cost make wax-matrix SRNA an attractive choice when drug therapy is indicated”.3 Keenan et al next studied 98 subjects taking 1500 mg of Endur-acin® and oat bran, each alone and in combination, finding good reductions in LDL and increases in HDL, and determined that very few patients (10%) experienced synergism from the combination.4 Another study by Keenan et al examined the effects of Endur-acin® in 158 hyperlipidemic patients comparing the efficacy and tolerability in younger (age 20 – 40) patients versus older (50-70) patients. Older patients taking 1500-2000mg demonstrated significantly greater improvements than younger patients in TC, LDL, TC/HDL ratio, and triglycerides. Side effects and toxicity were no greater in older subjects, and intolerance was 3.4%.5 Aronov et al randomized 89 subjects with elevated cholesterol into groups taking 1500 mg or 2000mg of Endur-acin®. This Russian population crossed over treatment after two months, followed by all subjects taking 2000mg in months five and six. TC, LDL, HDL, triglycerides, Apolipoproteins, and Lp(a) all improved, and dropout was 4.5%.7 Pasternak RC et al examined 91 patients with coronary heart disease and average lipid levels using a stepped-care combination protocol compared to placebo for 2.5 years. The six step algorithm utilized four drugs: pravastatin, SRNA (Endur-acin®), cholestyramine (Questrain®), and gemfibrozil (Lopid®), with a goal of achieving TC < 160 mg/dl, and a LDL/HDL ratio of less than 2.0. Endur-acin® was added to pravastatin in 40 of the 44 patients in the treatment group, and caused additional mean reductions in TC of 6%, LDL 11%, Trig 10% and increased HDL 8%. The combination produced changes of -26% TC, -39% LDL, -23% Trig, +17% HDL, -35% in TC/HDL, and -46% LDL/HDL. Most notably, the addition of Endur-acin® to pravastatin enabled an additional 43% to reach their target LDL levels, for a total of 94% of patients who were elevated at baseline.8 Three additional studies by Russian investigators have been published and presented at major cardiovascular symposiums as abstracts. In addition to the consistent effect on lipids, these abstracts report analytical findings on lipid transport, CETP activity, and fractional esterification in plasma.910 Finally, Keenan JM et al compared the safety and efficacy of Endur-acin®, inositol hexanicotinate (IHN), and placebo in 120 dyslipidemic patients, and found that all treatments were well tolerated, but IHN was no different than placebo on cholesterol fractions.11

In summary, investigators have found that wax-matrix Endur-acin® has consistently delivered good clinical results on all cholesterol sub-fractions, and is a very well tolerated formulation of SRNA, with dropout rates ranging from 3-4% (mean 4.5%), the lowest of any published niacin studies. In a 2005 review of key articles, guidelines and consensus papers relative to dyslipidemias, authors concluded that Endur-acin® (Endurance Products Co, Tigard, OR), was one of only two non-prescription SR niacin preparations that should be recommended.12 Physicians and patients must realize that all NA products are not alike or equivalent and that Endur-acin® is effective at doses lower than those often recommended for other forms of NA. Pharmacodynamic differences exist with different dosing regimens. Appropriate liver function monitoring should be done for all niacin products and regimens.

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