

May 16, 2011

STUDY CONDUCTED BY BIOFORTIS-PROVIDENT CLINICAL RESEARCH EXAMINES FOLIC ACID ABSORPTION RATES FROM SOFTGEL CAPSULE AND STANDARD TABLET

Bioavailability of Folic Acid Found to be Similar in both Formulations

Folic acid, an essential vitamin formulated to be part of a multivitamin + DHA liquid softgel capsule, is absorbed in amounts similar to folic acid formulated for solid tablets, according to a study presented by Dr. Kevin Maki, PhD, head of Biofortis-Provident Clinical Research, in a late breaking session at the Experimental Biology (EB) 2011 annual meeting. Different formulations, fillers and coatings of vitamin products may affect the degree or rate at which the product dissolves and releases its contents, which can alter the vitamin's absorption into the body and its bioavailability, a calculation of how much of a given dose of a compound reaches the blood stream.

Typically, folic acid supplements are sold in tablet form, but many consumers find softgel capsules easier to swallow than tablets. All women of childbearing age — especially those planning a pregnancy — are recommended by the U.S. Centers for Disease Control and Prevention to consume about 400 micrograms (μg) of folic acid daily to reduce the risk for neural tube defects during fetal development.

“With the increasing science on folic acid and the rise in popularity of softgel capsules, we felt it was important to examine the differences in vitamin formulations, specifically prenatal multivitamin with folic acid + DHA softgels versus tablets, and how that might affect their bioavailability. We found that softgels are just as effective as the tablets in delivering folic acid,” said study coauthor James Brooks, Ph.D., vice president of Science and Technology at Pharmavite, LLC, which conducted the study with investigators from Biofortis-Provident, Clinical in Glen Ellyn, IL.

The United States Pharmacopeia (USP) has disintegration and dissolution standards for dietary supplements. Current USP guidance exempts formulations for softgels, gelatin-based shells containing a liquid, from the dissolution standard, but Pharmavite, as a leading manufacturer of dietary supplements, seeks to have its products meet or exceed USP standards for quality, purity and composition through rigorous testing and inspections, explained Brooks.

Bioavailability of Folic Acid Similar between Softgel Capsules and Tablets

The folic acid in a multivitamin + DHA softgel was absorbed in the blood stream and provided systemic bioavailability at amounts similar to that from tablets. The rate of absorption from the softgels was slower than the tablet. Also, investigators documented that iron was absorbed from the softgel capsule, a secondary endpoint of the study.

In this crossover study, investigators randomly assigned 16 women, ages 18 to 45, to receive a single dose of either 800 μg folic acid in two tablets (Nature Made[®] Folic Acid 400 mcg) or 800 μg folic acid in a multivitamin + DHA softgel capsule (Nature Made[®] Prenatal Multi + DHA). Researchers then drew patients' blood samples prior to dosing and then at one, two, three, four, six and eight hours after dosing. About one week later, the women were tested with the alternate product. The women consumed low-folate meals during the testing period. Investigators did not know which product patients received during each phase until the study ended.

The average levels of total folate in the blood, a calculation called area under the curve (AUC), did not significantly differ between softgel capsules and tablets, 122.0 versus 112.2 hour x nanograms per milliliter respectively ($P = 0.562$). Also, the average peak plasma concentration of folate, a calculation called C_{max} , did not significantly differ, 49.0 vs. 43.1 nanomoles per liter for the softgels and tablets respectively, ($P = 0.259$).

About Folate

Folate, as well as its oxidized form folic acid, is a water-soluble B-vitamin that is essential for the synthesis and metabolism of nucleotides and amino acids, which have an important role in preventing fetal neural tube defects, such as spina bifida, during pregnancy. Recent evidence suggests that low folate ingestion may increase risks for cardiovascular disease and stroke, cancer, neuropsychiatric diseases and osteoporosis. Folic acid can be found in such foods as leafy green vegetables (spinach and turnip greens), citrus fruits and dried beans and peas, but also in food fortified with folate and folic acid supplements.

Experimental Biology Presentation

Wednesday, April 13, 2011, Late Breaking Poster # LB176

Absorption of Folic Acid is Similar from a Softgel Capsule and a Standard Tablet

Kevin C. Maki, Ph.D.; Kathleen M. Kelley, M.D.; Andrea L. Lawless, M.D.; Jocelyn M. Shields; and Mary R. Dicklin, Ph.D., of Biofortis-Provident Clinical, Glen Ellyn, IL; and Louis I. Ndife, Ph.D.; James R. Brooks, Ph.D.; and Shannon B. Wright, R.D., of Pharmavite, LLC, Northridge, CA.

About Experimental Biology 2011

Experimental Biology is an annual gathering of six scientific societies that this year is expected to draw 13,000-plus independent scientists and exhibitors. The American Association of Anatomists (AAA) is a co-sponsor of the meeting, along with the American Physiological Society (APS), American Society for Biochemistry and Molecular Biology (ASBMB), American Society for Investigative Pathology (ASIP), American Society for Nutrition (ASN) and the American Society for Pharmacology and Experimental Therapeutics (ASPET).

About Mérieux NutriSciences Corporation and Biofortis-Provident

With over 40 years of experience and part of Institut Mérieux, Mérieux NutriSciences Corporation helps advance science and solutions for food safety, quality and nutrition worldwide. Through its business units Silliker, Biofortis and Bioagri, it provides consulting, testing, auditing, education, sensory, innovation and contract research services.

Biofortis provides innovation for nutrition expert services to R&D professionals, including clinical trial services, as well as bioanalytical and sensory testing. Biofortis' geographical presence extends to Europe, the United States, China, and Brazil. Biofortis-Provident is a division of Biofortis and a leading contract research and consulting organization committed to advancing the science of chronic disease prevention by designing and conducting clinical trials.

About Pharmavite LLC:

For almost 40 years, Pharmavite LLC has earned and maintained the trust of healthcare professionals, consumers, and retailers by manufacturing high-quality vitamins, minerals and other dietary supplements, and all-natural foods under its Nature Made® and SOYJOY® brand names. Nature Made vitamins is the number one supplement brand in the food, drug, club and mass channels. SOYJOY is an all-natural, nutrient-rich food baked with whole soy and real fruit. Based in Northridge, California, Pharmavite LLC operates as a subsidiary of Otsuka Pharmaceutical Co., Ltd. For more information, please visit Pharmavite.com.

###

