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**FILE: ■ Milk Thistle (*Silybum marianum*)**  
**■ Chronic Liver Disease**  
**■ Cancer**

**HC 080372-345**

**Date: January 31, 2008**

**RE: Use of Milk Thistle to Treat Liver Disorders and Cancers**

Post-White J, Ladas EJ, Kelly KM. Advances in the use of milk thistle (*Silybum marianum*). *Integr Cancer Ther.* 2007;6(2):104-109.

Milk thistle (*Silybum marianum*) has been used for more than 2000 years to treat liver and biliary disorders. It is available in the United States as a dietary supplement and as such has not been approved by the U.S. Food and Drug Administration as a treatment for any medical condition. The authors examine the herb's history, mechanisms of action, safety and efficacy, and research.

The oldest reported use of milk thistle was by the ancient Greek physician Dioscorides, who recommended the herb as a treatment for serpent bites. During the Middle Ages, the herb was used as an antidote for liver toxins; later, the British herbalist Culpepper used milk thistle to relieve obstructions of the liver.<sup>1,2</sup> Native Americans have used it to treat boils and other skin diseases. The German Commission E recommends its use primarily for dyspeptic complaints and liver conditions, including toxin-induced liver damage and hepatic cirrhosis, and as a supportive therapy for chronic inflammatory liver conditions.<sup>3</sup>

Milk thistle is commonly used in gastrointestinal clinics in the United States to help treat hepatitis and cirrhosis and is one of the most commonly prescribed hepatoprotectants among patients with cancer. The authors report that the herb appears to help clear toxins from the blood and potentially aid patients in tolerating cancer therapy. It may also possess cancer cytotoxic properties.

Most early clinical trials investigated milk thistle's effectiveness in the treatment of patients with hepatitis, cirrhosis, or biliary disorders. The studies used a wide range of products and doses and yielded conflicting results, say the authors. And, although milk thistle has not significantly altered the course of chronic liver disease, it has reduced liver enzymes in some

studies and exhibited selected effects on anti-inflammatory measures in chronic liver disease and diabetes mellitus, as reported in two studies cited by the authors.

Milk thistle has only recently been examined in clinical trial testing for cancer treatment. The authors cite two studies. A study of 50 children with acute lymphoblastic leukemia with grade 2 or greater chemotherapy-related hepatotoxicity concluded that milk thistle was associated with a significant reduction in the liver enzyme test AST (aspartate aminotransferase) and a trend in reduction of ALT (alanine aminotransferase) levels after 56 days. In a phase III trial of men with prostate cancer, silymarin (the main active principle of milk thistle) along with soy isoflavones and other antioxidants delayed prostate-specific antigen level increases, whereas the placebo group had a 2.6-fold increase.

Silymarin, a flavonolignan complex, consists primarily of four flavonolignans, namely silybin, isosilybin, silychristin, and silydianin, roughly in the ratio 3:1:1:1. It is well known for its antioxidant and chemoprotectant effects on the liver. The authors report that strong preclinical evidence through in vitro and in vivo models shows that silymarin also interferes with the promotion and progression of cancer, particularly against prostate, breast, and ectocervical tumor cells.

Milk thistle has been used safely during pregnancy, in children, and in adults older than 75 years. The most commonly reported adverse events associated with its use are a mild laxative effect and gastrointestinal upset. The German Commission E reported no side effects of the herb within the recommended dose range.<sup>3</sup>

The authors conclude that milk thistle's effect on clinical outcomes is not well established, and reported effects on liver enzyme levels are inconsistent and inconclusive. The methodological quality of most clinical trials conducted in patients with chronic liver disease is low, with most of the studies including heterogeneous populations, lacking in standardized preparations, and having poorly defined nonobjective endpoints.<sup>4</sup> Additional clinical trials are needed to evaluate the potential of silymarin against liver toxicity, chronic liver disease, and human cancers by using standardized products and effective quality controls.

—Shari Henson

## References

<sup>1</sup>Flora K, Hahn M, Rosen H, et al. Milk thistle (*Silybum marianum*) for the therapy of liver disease. *Am J Gastroenterol*. 1998;93:139-143.

<sup>2</sup>Foster S. *Milk Thistle. Silybum Marianum*. Rev ed. Austin, Texas: American Botanical Council; 1999.

<sup>3</sup>Blumenthal M, Busse WR, Goldberg A, Gruenwald J, Hall T, Riggins CW, Rister RS, eds. Klein S, Rister RS, trans. *The Complete German Commission E Monographs: Therapeutic Guide to Herbal Medicines*. Austin, Texas: American Botanical Council; Boston: Integrative Medicine Communication; 1998.

<sup>4</sup>Verma S, Thuluvath PJ. Complementary and alternative medicine in hepatology: review of the evidence of efficacy. *Clin Gastroenterol Hepatol*. 2007 Apr;5(4):408-16.

The American Botanical Council has chosen not to reprint the original article.

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