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FILE: · **Ginkgo (*Ginkgo biloba*)**
· **Ginseng (Panax ginseng)**
Neurasthenia

DATE: February 22, 1999 HC 122481

RE: **Ginkgo/Ginseng Combination for Increased Mental Functions – Clinical Study**

K.A. Wesnes, R.A. Faleni, N.R. Hefting, G Hoogsteen, J.J.G. Houben, E. Jenkins, J.H.G. Jonkman, J. Leonard, O. Petrini and J.J. van Lier. The cognitive, subjective, and physical effects of a *Ginkgo biloba*/*Panax ginseng* combination in healthy volunteers with neurasthenic complaints. *Psychopharmacology Bulletin,* 1997, Vol. 33, pp. 677-683.

The extracts of leaves from the ginkgo tree contain ginkgo-flavone glycosides and terpenoids, which are known to have vasoregulating and blood viscosity-decreasing properties. A 1992 review of 40 studies concluded that ginkgo has positive effects in the treatment of cerebral insufficiency. Because of the large body of evidence suggesting that ginkgo's properties may improve cerebral insufficiency, ginkgo is widely prescribed in Western countries such as France and Germany for its treatment.

The roots of *Panax ginseng* C.A. Meyer contain several triterpene glycosides named ginsenosides (panaxosides), which are believed to contribute to the adaptogenic and physical performance-enhancing properties of ginseng extracts. They are used in traditional Chinese medicine to treat a large number of diseases, including neurasthenia, a condition associated with fatigue and tiredness. Ginko and ginseng are combined in *Gincosan* (Pharmaton SA, Switzerland), a product that contains 60 mg ginkgo and 100 mg ginseng standardized extracts.

The purpose of this trial was to explore the potential of the combination of the two products at different doses to alter the quality of cognitive function in volunteers diagnosed with neurasthenia. This population was selected because fatigue and tiredness, like that associated with the condition, may lead to reduced mental efficiency. To assess an even broader range of functions, other stress-related measures were included as outcomes to be measured.

Sixty-four volunteers (20 males, 44 females), age range 42 to 65, diagnosed with neurasthenia, were recruited for the trial and carefully screened for any other disease or medications. Those chosen for the 90-day, double-blind,

placebo-controlled, parallel-group study, were randomly assigned to four dosing groups, receiving 80, 160 or 320 mg of the combination twice a day or placebo. They received a single dose on day one. For the rest of the study period, the subjects received one of the following twice a day: two placebo capsules; one placebo capsule and one 80-mg capsule of the combination (30 mg *Ginkgo biloba* extract and 50 mg *Panax ginseng* extract); one placebo capsule and one 160-mg capsule of the combination (60 mg *Ginkgo biloba* extract and 100 mg *Panax ginseng* extract), or two 160-mg capsules of the combination. The subjects were assessed for cognitive function, stress-related performance and exercise ergometry. Assessments were done on the day before dosing and again at days 1, 30 and 90 at 1 hour after the morning dose and 1 hour after the afternoon dose. There were few side effects from the ginkgo/ginseng supplement. Reported side effects included dizziness, sleepiness and increased frequency of urination.

Overall, the study found that a combination of ginkgo and ginseng has beneficial effects on cognitive function. This was observed at assessments done 1 hour after the morning dosage on Day 90, one of the pre-defined endpoints of the study. However, an unexpected finding was that there was a reversal of the beneficial effects on cognitive function six hours later after the second dose was given. The authors suggest that perhaps a longer interval between doses may be necessary to avoid such a reversal. During exercise, at one hour after the morning dose on Day 90, the heart rate of subjects, another pre-defined endpoint, was lower for all doses compared to placebo. However, only the 90 mg dose was significantly lower. No other statistical differences in heart rate were seen between the placebo group and the treatment group. In the stress-related assessment, there were no statistical differences between placebo and treatment group. At the time of publication, a large international trial was currently under way in normal middle-aged volunteers to confirm and extend the present findings and to identify in greater detail the time course of the effects. *—Densie Webb, Ph.D.*

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