

January 10, 2011

### **Uptake of Lutein from MicroActive Lutein Esters**

A human study was conducted to compare the uptake of lutein from commercially available free lutein in oil formulation (FloraGlo lutein), lutein esters in oil formulation and the MicroActive lutein esters (micronized lutein esters) formulation using two subjects. The subjects were non-smokers, without any chronic diseases or gastrointestinal disturbances. The subjects were not taking any over-the-counter carotenoid supplements and were on their usual diets with modest amounts of carotenoids during the study. A single dose equivalent to 100 mg lutein was used for the study.

#### **Method**

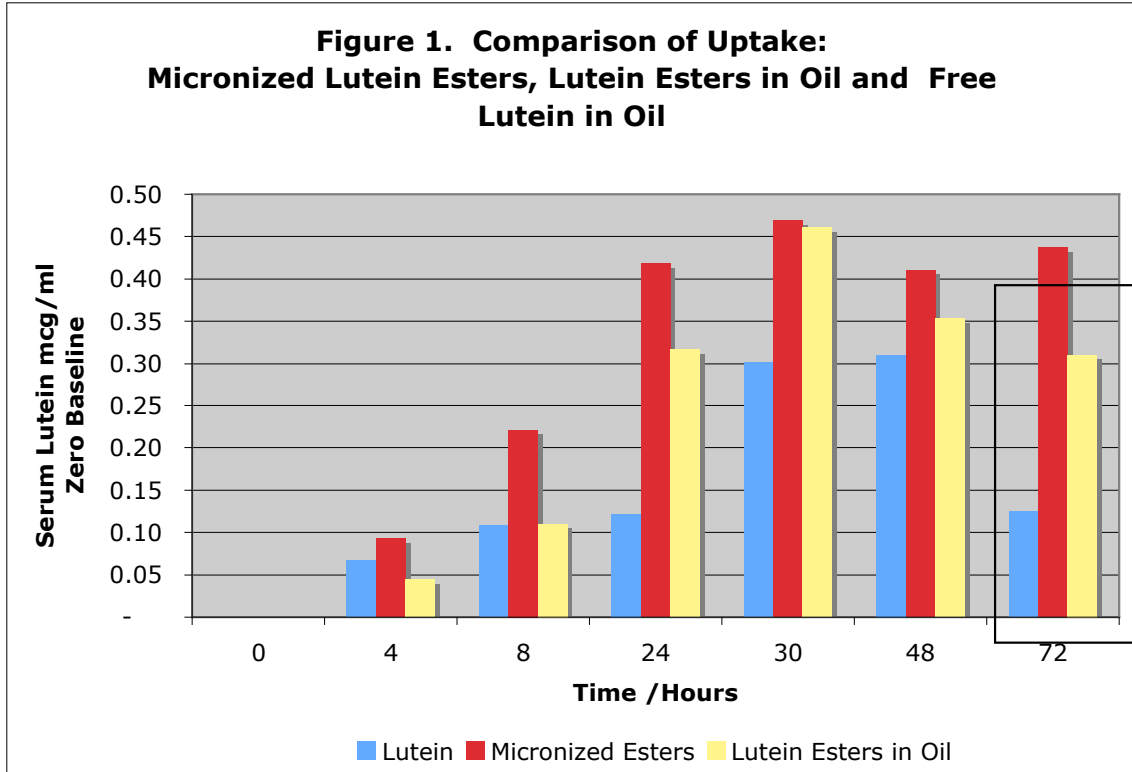
On the day of the study, 10 ml of blood was drawn to permit establishment of baseline values. After consumption of single doses of lutein from one of the formulations, blood samples were drawn at 4,8,24,30,48 and 72 hours. Serum was separated within 1hr of blood draw and frozen immediately at -70°C. After a two-week washout period, the study was repeated with the second formulation. The blood samples were drawn and processed as before. The third formulation was tested after a two-week washout period as described before.

Lutein and other carotenoids were extracted from the serum using Khachik's method (Khachik, F., Beecher, G.R., Goli, M.B., Lusby, W.R., and Daitch, C.E.,

“Separation and quantification of carotenoids in human plasma”, *Methods in Enzymol.*, 213: 205-219, 1992). The lutein concentration was determined using reverse phase HPLC and diode array detection.

## **Results**

Figure 1 presents the mean serum lutein levels adjusted to baseline. The serum lutein levels were higher at 4-24hrs with the MicroActive lutein ester formulation compared to free lutein in oil and lutein ester in oil formulations. The MicroActive lutein ester formulation also showed a tendency towards sustained release as evidenced by a higher serum lutein level at 72hrs compared to the other two formulations. Since the study was stopped at 72hrs, we were not able to measure the complete sustained release feature of the MicroActive lutein esters. Table 1 presents the area under the curve (AUC) for the three samples. Both subjects showed an increase in the uptake of lutein from the MicroActive lutein esters compared to free lutein or lutein esters in oil.



**Table 1. A Comparison of Uptake of Lutein from Micronized Lutein esters and Lutein in Oil.**

Subject	MicroActive Lutein Esters AUC <sub>0-72</sub> mcg/(ml*h)	Free Lutein in Oil AUC <sub>0-72</sub> mcg/(ml*h)	Lutein Esters in Oil AUC <sub>0-72</sub> mcg/(ml*h)
1	41.18	21.51	33.22
2	12.20	7.14	9.65
Average	26.69	14.32	21.44

While the sample size is too small for a formal statistical analysis, there is consistency in the percent increases by subject of micronized lutein esters over lutein esters in oil and free lutein in oil.

**Table 2. A Comparison of Percent Improvement of Micronized Lutein Esters Over**

## Oil Formulations

Subject	Percent Improvement Over Esters In Oil	Percent Improvement Over Free Lutein In Oil
1	24%	91%
2	26%	71%