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FloraGLO® Lutein: The Clinically Proven Lutein Brand
SUMMARY OF HUMAN CLINICAL TRIALS

KEY CONCLUSIONS

- *FloraGLO® Lutein is the most clinically researched lutein brand worldwide with over 80 peer-reviewed publications on human clinical trials.*
- *The eye health benefits of FloraGLO lutein are clinically proven with support from over 20 human clinical trials.*
- *More recent clinical research suggests that the health benefits of FloraGLO Lutein extend far beyond eye health, into skin and brain health and for both maternal and infant health.*
- *Finally, to date, there have been no reports of adverse events with FloraGLO supplementation, which further is backed by the fact that currently, FloraGLO is also the only lutein brand that has been used in infant supplementation trials.*

INTRODUCTION

FloraGLO® Lutein, a naturally-sourced unesterified lutein, is the most clinically researched lutein brand worldwide and the lutein brand used in the prestigious Age-Related Eye Disease Study II (AREDS2) conducted by the National Institutes of Health (NIH) National Eye Institute (NEI). Since its launch over 20 years ago into the marketplace, FloraGLO is the brand that has been routinely selected by leading reasearchers, supplement and food manufacturers because of its established reputation for quality, safety and efficacy.

Over the past 20 years, there have been over 80 peer-reviewed scientific publications assessing the effects of FloraGLO Lutein in human subjects. Since it is critical for manufacturers to formulate with an ingredient that has excellent performance in different formulations and the clinical evidence to substantiate health benefits, manufacturers using FloraGLO Lutein are assured an ingredient with established scientific support and proven benefits. A closer look at these over 80 scientific publications assessing FloraGLO available through PubMed[1] as of November 1, 2017 reveals— 30 on visual function and performance; 34 assessing macular pigment optical density (MPOD) levels and 36 measuring serum or plasma lutein concentrations, both markers of long term and short term intake of lutein, respectively; 4 on skin health, 6 on brain health and cognitive function, and 4 showing support for blue light filtering[2] These trials have supplemented with FloraGLO Lutein at doses ranging from 1.7 to 40 mg per day for time periods of up to five years (see tables for details).

Since lutein is deposited in the macula and lens of the eye, many clinical trials using FloraGLO have focused on lutein's protective role in eye health. This protection is suggested to stem from the ability of lutein to act as "internal sunglasses" by absorbing blue light (*1, 2*), act as an antioxidant to neutralize free radicals and reduce inflammatory markers (*3*). However, more recently, there has been mounting support for FloraGLO lutein's beneficial role in other aspects of human health including-- skin health, brain health/cognitive function, and maternal and infant nutrition. FloraGLO Lutein is also the only lutein, to date, that is Generally Recognized As Safe (GRAS) for use in infant formula, both term and premature infant formula (GRN 221 and 390). Therefore, it should also not be surprising that currently FloraGLO Lutein is the only lutein brand that has been used as the sole source of lutein in all 14 supplementation trials regarding infant health.

[1]Pubmed is maintained by the United States National Library of Medicine (NLM) at the National Institutes of Health and is considered to be the most comprehensive (with more than 27 million references to journal articles) for searches of this kind.
[2]Consists of short wavelengths of light in the blue region of the visible light spectrum.

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More commonly, FloraGLO Lutein supplementation trials reporting benefits have used doses between 6-10 mg lutein per day. However, with the global average daily intake of lutein and zeaxanthin estimated at less than 3 mg (*4-9*) (Figure 1), far below lutein intakes necessary to support eye, skin and brain health, there is clearly a critical need to increase the intake of this important nutrient through diet or supplementation. Also, noteworthy, lutein concentrations in the macula naturally deplete as people age (*10*), which can also compound the current population inadequacy.

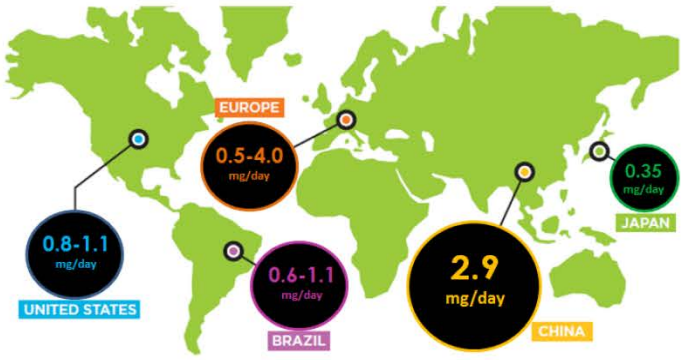

Fig 1. Average daily intake of lutein and zeaxanthin across the world.

Nonetheless, foods rich in lutein as well as supplements or food fortified with FloraGLO Lutein can bridge this gap and provide lutein benefits for eye, skin and brain health. Importantly, supplementation trials have shown FloraGLO not only to be bioavailable, but also exhibit comparable bioavailability to the lutein obtained from foods rich in lutein (54, 61, 93, 94).

HUMAN CLINICAL TRIALS WITH FLORAGLO LUTEIN

The following pages tabulate all the publically available peer-reviewed science carried out with FloraGLO lutein in human subjects to date[3]. The tables are organized as follows:

Eye Health

- FloraGLO Lutein Supplementation on Visual Function and Performance
  - Table 1. FloraGLO Lutein Supplementation on Visual Function and Performance in Healthy Subjects
  - Table 2. FloraGLO Lutein Supplementation on Blue Light in Healthy Subjects
    - Please note: Studies demonstrating an increase in MPOD (measured with heterochromatic flicker photometry (HFP) or indirectly with other methods) with FloraGLO supplementation indicate that FloraGLO lutein filters more of the blue light focused on the fovea. (See Tables 7-8)
  - Table 3. FloraGLO Lutein Supplementation on Visual Function and Performance in Subjects with Ocular Diseases

Brain Health And Cognitive Function

- Table 4. FloraGLO Lutein Supplementation on Cognitive Function

Skin Health

- Table 5. FloraGLO Lutein Supplementation on Skin Health

Maternal and Infant Nutrition and Health

- Table 6. FloraGLO Lutein Supplementation on Maternal and Infant Health

Uptake, Absorption and Bioavailability

- FloraGLO Lutein Supplementation on Markers of Lutein Intake
  - Table 7. Long-Term Marker of Lutein Intake, MPOD in Healthy Subjects
  - Table 8. Long-Term Marker of Lutein Intake, MPOD in Subjects with Ocular Diseases
  - Table 9. Short-Term Marker of Lutein Intake, Serum/Plasma Lutein in Healthy Subjects
  - Table 10. Short-Term Marker of Lutein Intake, Serum/Plasma Lutein in Subjects with Ocular Diseases

Other Health Related Outcomes

- Table 11. FloraGLO Lutein Supplementation on Other Health-Related Outcomes

[3] November 1, 2017.

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EYE HEALTH

FLORAGLO LUTEIN SUPPLEMENTATION ON VISUAL FUNCTION AND PERFORMANCE

Table 1. FloraGLO Lutein Supplementation on Visual Function and Performance in Healthy Subjects

Trial	Cohort[a]	Protocol[b]	Effect on Visual Function[c]
Obana *et al.* 2015 (*84*)	18 healthy adults	10.5 mg FloraGLO for 6 months	Significant improvement in glare sensitivity in retinal responders (13 of 18 subjects)
Bovier *et al.* 2015 (*14*)	25 healthy young adults	8 mg FloraGLO and 26 mg zeaxanthin/day for 4 months	Significant increase in temporal contrast sensitivity as compared to placebo
Hammond et al. 2014 (*16*)	57 healthy young adults	10 mg FloraGLO and 2 mg zeaxanthin/day for 1 year	Significant improvement on photostress recovery time as compared to placebo. Improvement in glare recovery not statistically significant.
Bovier *et al.* 2014 (*17*)	25 healthy young adults	8 mg FloraGLO and 26 mg zeaxanthin/day for 4 months	Significantly improved critical flicker fusion threshold as compared to placebo
Pescosolido *et al.* 2012 (*22*)	24 healthy males	18 mg FloraGLO/day for 45 days	Improved Visual Evoked Potentials (VEP) by showing a significant decrease of latency increase of amplitude as compared to placebo
Loughman *et al.* 2012 (*23*)	12 healthy adults	20 mg FloraGLO and 2 mg zeaxanthin/day for 6 months	Significant improvement in mesopic contrast sensitivity at 6.0 cycles per degree (cpd) as compared to baseline
Stringham *et al.* 2008 (*28*)	40 healthy young adults	10 mg FloraGLO and 2 mg zeaxanthin/day for 6 months	Significant increase in glare tolerance and photostress recovery time as compared to baseline
Kvansakul *et al.* 2006 (*31*)	15 healthy males	10 mg FloraGLO and/or 10 mg zeaxanthin/day for 6 months	Significant improvement in contrast acuity as compared to placebo. Non-significant, decreasing trend in light scatter and wavefront aberrations as compared to placebo.
Morganti *et al.* 2004 (*32*)	20 healthy smokers	6 mg FloraGLO/day for 2 months	Significant increase in global visual activity as compared to placebo

[a]Only subjects who received FloraGLO supplementation are listed. [b]Only FloraGLO dose is listed. Trial may have included other nutrients. [c]Statistical significance defined as $p < 0.05$. Publications reporting significant results are reported in blue.

Table 2. FloraGLO Lutein Supplementation on Blue Light in Healthy Subjects

Trial	Cohort[a]	Protocol[b]	Effect on Eye Health[c]
Rodriguez-Carmona *et al.* 2006 (*47*)	13 healthy males	10 mg FloraGLO/day for 6 months followed by 20 mg FloraGLO/day for additional 6 months or 10 mg FloraGLO/day and 10 mg zeaxanthin/day for 6-12 months	Uniform reductions in percent transmitted blue light in the central and paracentral region around the fovea over ±4° eccentricity at 6 months supplementation as compared to placebo. Lower transmittance of blue light in supplemented group compared to placebo was also observed 4 months after termination of supplementation at foveal center ±2°. No correlation was found between MPOD and yellow-blue color detection thresholds
Stringham *et al.* 2008 (*28*)	40 healthy young adults	10 mg FloraGLO and 2 mg zeaxanthin/day for 6 months	Subjects could tolerate a significantly greater amount of veiling glare at 4 and 6 months
Kvansakul et al. 2006 (*31*)	15 healthy males	10 mg FloraGLO and/or 10 mg zeaxanthin/day for 6 months	Light scattering in the eye and the root-mean-square wavefront aberrations showed decreasing trends as a result of supplementation

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Hammond *et al.* 2014 (*16*)	57 healthy young adults	10 mg FloraGLO and 2 mg zeaxanthin/day for 1 year	Chromatic contrast, measured by having subjects adjust a circular blue surround until it caused the disappearance of a circular yellow grating target, improved significantlyas compared to placebo

[a]Only subjects who received FloraGLO supplementation are listed. [b]Only FloraGLO dose is listed. Trial may have included other nutrients.
[c]Statistical significance defined as $p < 0.05$. Publications reporting significant results are reported in blue.

Table 3. FloraGLO Lutein Supplementation on Visual Function and Performance in Subjects with Ocular Diseases

Trial	Cohort[a]	Protocol[b]	Effect on Visual Function[c]
Shinojima *et al.* 2017 (*95*)	37 patients with chronic central serous chorioretinopathy	15 mg FloraGLO/day for 6 months	Significant increase in best-corrected visual acuity as compared to baseline with a significant reduction rate in serous retinal detachment height
Corvi *et al.* 2017 (*80*)	20 patients with medium/large drusen and 19 with reticular pseudodrusen	10 mg FloraGLO and 2 mg zeaxanthin/day for 3 months	No significant change in retinal sensitivity and best corrected visual acuity
Kawashima *et al.* 2016 (*81*)	20 adults with dry eye	6 mg FloraGLO for 8 weeks	Clinical symptoms of dry eye were significantly improved. There was a trend on increased tear production observed with the Schimmer test
Kovalevskaya *et al.* 2015 (*82*)	60 patients with dry age-related macular degeneration (AMD)	12 mg FloraGLO and 1 mg zeaxanthin/day for 3 months	Significant beneficial effects on macular function (decrease in the number of defects per eye and volume lost relative to the hill-of-vision) as compared to baseline
Moshetova *et al.* 2015 (*83*)	180 patients with diabetic retinopathy or with combined fundus pathology	12 mg FloraGLO and 1 mg zeaxanthin/day for 1 month with other supplements at different doses	Improved visual acuity, macular thickness, and light sensitivity after supplementation
Wolf-Schnurrbusch *et al.* 2015 (*85*)	79 patients with AMD	10 mg FloraGLO for 6 months	Significant improvement in contrast sensitivity
Sabour-Pickett *et al.* 2014 (*15*)	17 adults with early AMD	20 mg FloraGLO and 2 mg zeaxanthin/day for 1 year	Significant increase in contrast sensitivity at low spatial frequencies as compared to placebo
AREDS 2, 2013 (*18*)	2107 adults (age 50-85) with AMD	10 mg FloraGLO and 2 mg zeaxanthin/day for 5 years	No change in visual acuity ($p = 0.50$) as compared to placebo
Chew (AREDS2 Report #4) 2013 (*19*)	2107 adults (age 50-85) with AMD	10 mg FloraGLO and 2 mg zeaxanthin/day for 5 years	No change on the rates of cataract surgery ($p=0.54$) or vision loss ($p=0.20$) as compared to placebo. In participants in the lowest quintile of dietary intake of lutein and zeaxanthin, hazard ratio for cataract surgery was significantly reduced comparing lutein/zeaxanthin vs no lutein/zeaxanthin supplementation
Chew (AREDS2 Report #3) 2014 (*20*)	2107 adults (age 50-85) with AMD	10 mg FloraGLO and 2 mg zeaxanthin/day for 5 years	Significant reduction in AMD disease progression in patients supplemented with lutein/zeaxanthin as compared to those did not receive lutein/zeaxanthin
Dawczynski *et al.* 2013 (*21*)	105 AMD patients	10 mg FloraGLO and 1 mg zeaxanthin/day or 20 mg FloraGLO and 3 mg zeaxanthin/day for 1 year	Significant increase in visual acuity as compared to placebo
Piermarocchi *et al.* 2011(*24*)	103 AMD patients	10 mg FloraGLO and 1 mg zeaxanthin/day for 2 years	Significant increase in visual acuity, contrast sensitivity and National Eye Institute Visual Function Questionnaire score as compared to placebo
Sasamoto *et al.* 2011 (*25*)	43 Japanese subjects (5 normal, 5 with central serous chorioretinopathy and 33 with AMD); Only healthy eyes included in study	6 mg FloraGLO/day for 12 months	Significant increase in contrast sensitivity and retinal sensitivity as compared to baseline
Berson *et al.* 2010 (*26*)	110 retinitis pigmentosa patients	12 mg FloraGLO/day for 4 years	Significant reduction in the loss of midperipheral field sensitivity as compared to placebo

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Parisi *et al.* 2008 (*27*)	15 AMD patients	10 mg FloraGLO/day for 12 months	Significant increase in multifocal electroretinogram response amplitude densities as compared to placebo
Aleman *et al.* 2007 (*29*)	8 Stargardt disease and 3 cone–rod dystrophy patients	20 mg FloraGLO/day for 6 months	No change in foveal sensitivity ($p > 0.05$) as compared to baseline
Bahrami *et al.* 2006 (*30*)	34 retinitis pigmentosa patients	10 mg FloraGLO/day for 3 months followed by 30 mg FloraGLO/day for 3 months	Significantly improved visual field as compared to placebo. Non-significant increase in visual acuity ($p=0.58$) and contrast sensitivity ($p=0.34$)
Richer *et al.* 2004 (*33*)	59 AMD patients	10 mg FloraGLO/day for 12 months	Significant improvements in contrast sensitivity, visual acuity, glare recovery, and photostress recovery as compared to baseline
Falsini *et al.* 2003 (*34*)	17 AMD patients and 4 healthy subjects	15 mg FloraGLO/day for 6.5 months	Significant increase in macular focal electroretinogram parameters amplitude and modulation threshold as compared to baseline
Aleman *et al.* 2001 (*35*)	23 patients with retinal degeneration and 8 healthy subjects	20 mg FloraGLO/day for 6 months	Non-significant increase in visual acuity and foveal sensitivity ($p=0.33$) as compared to baseline
Dagnelie *et al.* 2000 (*36*)	13 retinitis pigmentosa patients and 3 with other retinal degenerations	40 mg FloraGLO/day for 9 weeks followed by 20 mg FloraGLO/day for 17 weeks	Significant improvement in mean visual acuity and central visual field as compared to baseline

[a]Only subjects who received FloraGLO supplementation are listed. [b]Only FloraGLO dose is listed. Trial may have included other nutrients. [c]Statistical significance defined as $p < 0.05$. Publications reporting significant results are reported in blue.

BRAIN HEALTH AND COGNITIVE FUNCTION

Table 4. FloraGLO Lutein Supplementation on Cognitive Function

Trial	Cohort[a]	Protocol[b]	Effect on Cognitive Function[c]
Hammond et al. 2017 (*96*)	36 community-dwelling older adults	10 mg FloraGLO and 2 mg zeaxanthin/day for 1 year	Significant improvement in complex attention and cognitive flexibility as compared to placebo; there was also a trend toward significant effect on executive function domain; males in the FloraGLO group also had a significant improvement in the composite memory domain.
Lindbergh et al. 2017 (*97*)	30 community-dwelling older adults	10 mg FloraGLO and 2 mg zeaxanthin/day for 1 year	Significant increases in blood-oxygen-level-dependent signal in the supplement group in the left dorsolateral prefrontal cortex and anterior cingulate cortex as compared to baseline; supplementation significantly influenced brain function on a verbal learning task relative to placebo
Chew *et al.* 2015 (*87*)	2107 adults (age 50-85) with AMD	10 mg FloraGLO and 2 mg zeaxanthin/day for 5 years	Significant improvement in Wechsler logical memory II test as compared to participants without FloraGLO/zeaxanthin
Bovier *et al.* 2015 (*14*)	25 healthy young adults	8 mg FloraGLO and 26 mg zeaxanthin/day for 4 months	Significant increase in temporal processing speed as compared to placebo
Bovier *et al.* 2014 (*17*)	25 healthy young adults	8 mg FloraGLO and 26 mg zeaxanthin/day for 4 months	Significantly improved motor reaction time as compared to placebo
Johnson *et al.* 2008 (*78*)	25 healthy women	12 mg FloraGLO/day for 4 months (with & without DHA)	Significant improvement in verbal fluency scores in DHA, lutein and combined groups; memory scores and rate of learning improved significantly in the combined treatment group as compared to baseline

[a]Only subjects who received FloraGLO supplementation are listed. [b]Only FloraGLO dose is listed. Trial may have included other nutrients.
[c]Statistical significance defined as $p < 0.05$. Publications reporting significant results are reported in blue.

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SKIN HEALTH

Table 5. FloraGLO Lutein Supplementation on Skin Health

Trial	Cohort[a]	Protocol[b]	Effect on Skin Health[c]
Morganti *et al.* 2008 (*75*)	20 healthy females	Unspecified dose of FloraGLO Lutein for 3 months applied topically	Significant decrease in transepidermal water loss; significant increase in hydration, skin lipids, elasticity and clinical scores of wrinkling, hyperpigmentation, roughness and laxity as compared to placebo
Palombo *et al.* 2007 (*76*)	30 healthy females	10 mg FloraGLO/day orally alone or in combination with 100 ppm FloraGLO/day topically for 3 months	Significant decrease in skin lipid peroxidation; significant increase in skin lipids, hydration, and elasticity as compared to placebo
Morganti *et al.* 2004 (*32*)	20 healthy smokers	6 mg FloraGLO/day orally for 2 months	Significant increase in skin lipids as compared to baseline
Morganti *et al.* 2002 (*77*)	20 healthy females	6 mg FloraGLO/day orally for 2 months	Significant decrease in skin lipid peroxidation; significant increase in skin lipids and hydration as compared to baseline

[a]Only subjects who received FloraGLO supplementation are listed. [b]Only FloraGLO dose is listed. Trial may have included other nutrients.
[c]Statistical significance defined as $p < 0.05$. Publications reporting significant results are reported in blue.

MATERNAL AND INFANT NUTRITION

Table 6. FloraGLO Lutein Supplementation on Maternal and Infant Health

Trial	Cohort[a]	Protocol[b]	Effect on Infant/Maternal Health[c]
Lasekan *et al.* 2015 (*86*)	126 healthy term infants aged 0-8 days	Formula with 53 µg FloraGLO/L for 28 days	Growth equivalence to control formula and no significant differences in formula tolerance
Kon *et al.* 2014 (*65*)	23 full term infants age 10 days - 2 months	Formula with 11.4 µg FloraGLO/100mL supplemented for 28 days	Growth equivalence to control formula and no significant differences in formula tolerance
Perrone *et al. 2014 (66)*	103 healthy newborn infants	0.28 mg FloraGLO (two doses: one each at 6 and 36 hours of life)	Significantly higher biological antioxidant potential (BAP) as compared to control
Sherry *et al.* 2014 (*52*)	89 post-partum women	6 or 12 mg FloraGLO daily for 6 weeks	Significant increase of lutein in breast milk in mothers and plasma lutein in infants as compared to placebo
Lorenzoni *et al* 2013 (*67*)	12 pregnant women with gestational diabetes	10 mg FloraGLO and 2 mg zeaxanthin for 12-14 weeks	Significantly lower total hydroperoxides in infants at 2 hours old as compared to control
Costa *et al.* 2013 (*68*)	38 infants with gestational age ≤ 34 weeks + 7 days	0.5 mg FloraGLO + 0.02 mg zeaxanthin/kg/day until 40th week post-menstrual age (PMA) or discharge	No significant effect on total antioxidant status (TAS) as compared to placebo ($p>0.05$). Significant linear correlation between plasma lutein concentration and TAS
Mackey *et al.* 2013 (*69*)	41 full term infants between age 14 and 35 days	Formula with 32.6 µg FloraGLO/L or 52.6 µg FloraGLO/L	Significant increase in serum lutein as compared to placebo for high dose formula. Non –significant increase for low dose formula.
Manzoni *et al.* 2013 (*70*)	113 infants with gestational age <32 weeks + 6 days (mean 30 weeks)	0.14 mg FloraGLO + 0.6 µg zeaxanthin/day from birth until 36 weeks corrected gestational age	Non-significant reduction in threshold retinopathy of prematurity ($p=0.18$), necrotizing enterocolitis ($p=0.15$), and bronchopulmonary dysplasia ($p=0.07$) as compared to placebo
Romagnoli *et al.* 2011 (*71*)	31 preterm infants with gestational age ≤32 weeks	0.5 mg FloraGLO/kg/day and 0.02 mg zeaxanthin/kg/day from seventh day of life until 40 weeks PMA or until discharge	Not effective in preventing or reducing severity retinopathy of prematurity (ROP) as compared to placebo

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Dani *et al.* 2012 (*72*)	58 infants gestational age <32 weeks (mean 28 weeks)	0.14 mg FloraGLO + 0.006 mg zeaxanthin/day from day 1-7 (mean 5.5 days) until discharge (mean 47 days).	Not effective in preventing retinopathy of prematurity (ROP) as compared to placebo
Rubin *et al.* 2012 (*73*)	92 infants > 33 weeks gestational age	Formula containing 211 µg/L FloraGLO until discharge at 40 weeks post-menstrual age (PMA) and 68.7 µg/L FloraGLO from 40 to until 50 weeks PMA.	Significant increase in plasma lutein and rod photoreceptor sensitivity as compared to placebo. Significant decrease in plasma C-reactive protein (CRP) at 40 weeks as compared to placebo. Significant correlation between plasma lutein concentrations and saturated response amplitude in rod photoreceptors at 50 weeks PMA. No group differences in growth, feeding tolerance or adverse events.
Capeding *et al.* 2010 (*11*)	115 infants > 14 days	Formula with 200 µg FloraGLO Lutein per liter for 16 weeks	Growth equivalence to control formula
Romagnoli *et al.* 2010 (*56*)	10 preterm infants	Single dose of 0.5 mg FloraGLO/kg	Increase in serum lutein as compared to baseline (statistics not run)
Perrone *et al.* 2010 (*13*)	10 healthy term newborns	0.28 mg FloraGLO orally at 12 and 36 hr after birth.	Significantly lower total hydroperoxides (TH) and significantly increased biological antioxidant potential (BAP) as compared to placebo.
Bettler *et al.* 2010 (*74*)	20 healthy term (37 to 42 weeks gestation) formula-fed infants between 9 and 16 days of age	Formula with 45, 120, or 225 µg FloraGLO/L	Significant increase in serum lutein and normal growth was observed as compared to unfortified, control formula.

[a]Only subjects who received FloraGLO supplementation are listed. [b]Only FloraGLO dose is listed. Trial may have included other nutrients.
[c]Statistical significance defined as $p < 0.05$. Publications reporting significant results are reported in blue.

UPTAKE, ABSORPTION AND BIOAVAILABILITY

FLORAGLO LUTEIN SUPPLEMENTATION ON MARKERS OF LUTEIN INTAKE

Table 7. Long-Term Marker of Lutein Intake, MPOD in Healthy Subjects

Trial	Cohort[a]	Protocol[b]	Effect on MPOD[c]
Hammond et al. 2017 (*96*)	36 community-dwelling older adults	10 mg FloraGLO and 2 mg zeaxanthin/day for 1 year	Significant increase in MPOD as compared to baseline and placebo
Lindbergh et al. 2017 (*97*)	30 community-dwelling older adults	10 mg FloraGLO and 2 mg zeaxanthin/day for 1 year	Significant increase in MPOD over time as well as compared to placebo
Korobelnik *et al.* 2017 (*98*)	60 healthy adults whose parents had neovascular AMD	10 mg FloraGLO and 2 mg zeaxanthin/day for 6 months	No significant change in MPOD as compared to baseline
Obana *et al.* 2015 (*84*)	18 healthy adults	10.5 mg FloraGLO for 6 months	No change in MPOD as compared to baseline (p=0.50)
Bovier *et al.* 2015 (*14*)	25 healthy young adults	8 mg FloraGLO and 26 mg zeaxanthin/day for 4 months	Significant increase in MPOD as compared to placebo
Hammond *et al.* 2014 (*16*)	57 healthy young adults	10 mg FloraGLO and 2 mg zeaxanthin/day for 1 year	Significant increase in MPOD as compared to placebo
Bovier *et al.* 2014 (*17*)	25 healthy young adults	8 mg FloraGLO and 26 mg zeaxanthin/day for 4 months	Significant increase in MPOD as compared to placebo
Loughman *et al.* 2012 (*23*)	12 healthy adults	20 mg FloraGLO and 2 mg zeaxanthin/day for 6 months	Non-significant increase in MPOD with respect to baseline (p>0.05 for all measured eccentricities)
Nolan *et al.* 2012 (*40*)	11 healthy adults	20 mg FloraGLO/day for 8 weeks	No change in MPOD with respect to baseline (p>0.05)

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Tanito *et al.* 2012 (*41*)	11 healthy adults	10 mg FloraGLO and 0.8 mg zeaxanthin/day for three months	Significant increase in MPOD with respect to baseline
Hammond *et al.* 2012 (*42*)	322 healthy female twins	18 mg FloraGLO and 2.4 mg zeaxanthin per day for 6 months	Significant increase in MPOD with respect to baseline
Johnson *et al.* 2008 (*43*)	25 healthy older women	12 mg FloraGLO/day for 4 months	Significant increase in MPOD as compared to baseline
Stringham *et al.* 2008 (*28*)	40 healthy young adults	10 mg FloraGLO and 2 mg zeaxanthin/day for 6 months	Significant increase in MPOD as compared to baseline
Schalch *et al.* 2007 (*45*)	13 healthy males	10 mg FloraGLO/day for 6 months followed by 20 mg FloraGLO/day for additional 6 months or 10 mg FloraGLO/day and 10 mg zeaxanthin/day for 6-12 months	Significant increase in MPOD as compared to placebo
Franciose *et al.* 2006 (*46*)	32 healthy adults	4-6 mg FloraGLO/day for 12 weeks	No change in mean MPOD with respect to baseline ($p>0.05$)
Kvansakul *et al.* 2006 (*31*)	13 healthy males	10 mg FloraGLO/day for 6 months followed by 20 mg FloraGLO/day for additional 6 months or 10 mg FloraGLO/day and 10 mg zeaxanthin/day for 6-12 months	Significant increase in MPOD as compared to placebo
Rodriguez-Carmona *et al.* 2006 (*47*)	13 healthy males	10 mg FloraGLO/day for 6 months followed by 20 mg FloraGLO/day for additional 6 months or 10 mg FloraGLO/day and 10 mg zeaxanthin/day for 6-12 months	Significant increase in MPOD as compared to placebo
Morganti *et al.* 2004 (*32*)	20 healthy adults	6 mg FloraGLO/day for 2 months	Significant increase in MPOD as compared to baseline
Cardinault *et al.* 2003 (*48*)	12 healthy young and 17 healthy elderly	9 mg FloraGLO/day for 5 weeks	No change in MPOD with respect to baseline ($p>0.05$)
Schweitzer *et al.* 2002 (*50*)	10 healthy adults	6 mg FloraGLO/day for 40 days	Non-significant increase in MPOD with respect to baseline

[a]Only subjects who received FloraGLO supplementation are listed. [b]Only FloraGLO dose is listed. Trial may have included other nutrients.
[c]Statistical significance defined as $p < 0.05$. Publications reporting significant results are reported in blue.

Table 8. Long-Term Marker of Lutein Intake, MPOD in Subjects with Ocular Diseases

Trial	Cohort[a]	Protocol[b]	Effect on MPOD[c]
Corvi *et al.* 2017 (*80*)	20 patients with medium/large drusen and 19 with reticular pseudodrusen	10 mg FloraGLO and 2 mg zeaxanthin/day for 3 months	Significant increase in MPOD in patients with reticular pseudodrusen
Wolf-Schnurrbusch *et al.* 2015 (*85*)	79 patients with AMD	10 mg FloraGLO for 6 months	Significant increase in MPOD as compared to baseline
Akuffo *et al. 2015 (37)*	13 AMD patients	20 mg FloraGLO and 0.86 mg zeaxanthin/day for 3 weeks	Significant increase in MPOD as compared to baseline
Sabour-Pickett *et al.* 2014 (*15*)	17 adults with early AMD	20 mg FloraGLO and 2 mg zeaxanthin/day for 1 year	Significant increase in MPOD for 1.75° eccentricity as compared to baseline. Non-significant increases for all other eccentricities ($p>0.05$)
García-Layana *et al. 2013 (38)*	23 AMD patients	12 mg FloraGLO/day for 1 year	Significant increase in MPOD as compared to placebo

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Dawczynski *et al.* 2013 (*21*)	105 AMD patients	10 mg FloraGLO and 1 mg zeaxanthin/day or 20 mg FloraGLO and 3 mg zeaxanthin/day for 1 year	Significant increase in MPOD as compared to placebo
Arnold *et al.* 2013 (*39*)	104 AMD patients	10 mg FloraGLO and 1 mg zeaxanthin/day or 20 mg FloraGLO and 2 mg zeaxanthin/day for 12 months	Significant increase in MPOD at both doses as compared to placebo
Sasamoto *et al.* 2011(*25*)	43 Japanese subjects (5 normal, 5 with central serous chorioretinopathy and 33 with AMD); Only healthy eyes included in study	6 mg FloraGLO/day for 12 months	No change in MPOD with respect to baseline (p=0.261 at the end of 12 months)
Berson *et al.* 2010 (*26*)	110 retinitis pigmentosa patients	12 mg FloraGLO/day for 4 years	Significant increase in MPOD as compared to placebo
Aleman *et al.* 2007 (*29*)	8 Stargardt disease and 3 cone–rod dystrophy patients	20 mg FloraGLO/day for 6 months	63% of patients experienced a significant increase in MPOD as compared to baseline
Richer *et al.* 2007 (*44*)	59 AMD patients	10 mg FloraGLO/day for 12 months	Significant increase in MPOD with no plateau as compared to baseline
Richer *et al.* 2004 (*33*)	59 AMD patients	10 mg FloraGLO/day for 12 months	Significant increase in mean MPOD as compared to baseline
Duncan *et al.* 2002 (*49*)	7 choroideremia (form of retinal degeneration) patients	20 mg FloraGLO/day for 6 months	Significant increase in mean MPOD as compared to baseline
Aleman *et al.* 2001 (*35*)	23 patients with retinal degeneration and 8 healthy subjects	20 mg FloraGLO/day for 6 months	Significant increase in MPOD as compared to baseline

[a]Only subjects who received FloraGLO supplementation are listed. [b]Only FloraGLO dose is listed. Trial may have included other nutrients.
[c]Statistical significance defined as p <0.05. Publications reporting significant results are reported in blue.

Table 9. Short-Term Marker of Lutein Intake, Serum/Plasma Lutein in Healthy Subjects

Trial	Cohort[a]	Protocol[b]	Effect on Serum Lutein Level[c]
Hammond et al. 2017 (*96*)	36 community-dwelling older adults	10 mg FloraGLO and 2 mg zeaxanthin/day for 1 year	Significant increase in serum lutein as compared to placebo
Korobelnik et al. 2017 (*98*)	60 healthy adults whose parents had neovascular AMD	10 mg FloraGLO and 2 mg zeaxanthin/day for 6 months	Significant increase in plasma lutein as compared to baseline and placebo
Obana *et al.* 2015 (*84*)	18 healthy adults	10.5 mg FloraGLO for 6 months	Significant increase in serum lutein as compared to baseline
Hammond *et al.* 2014 (*16*)	57 healthy young adults	10 mg FloraGLO and 2 mg zeaxanthin/day for 1 year	Significant increase in serum lutein as compared to placebo
Borel *et al.* 2014 (*51*)	40 healthy adults	15 mg FloraGLO single dose	Significant increase in serum lutein as compared to baseline
Sherry *et al.* 2014 (*52*)	89 post-partum women	6 or 12 mg FloraGLO daily for 6 weeks	Significant increase in serum lutein for both mothers and breast fed infants as compared to baseline and placebo
Loughman *et al.* 2012 (*23*)	12 healthy adults	20 mg FloraGLO and 2 mg zeaxanthin/day for 6 months	Non-significant increase in serum lutein as compared to baseline (p=0.14)
Evans *et al.* 2013 (*54*)	48 healthy adults	20 mg FloraGLO single dose	Significant increase in serum lutein as compared to baseline
Hammond *et al.* 2012 (*42*)	322 healthy female twins	18 mg FloraGLO and 2.4 mg zeaxanthin per day for 6 months	Significant increase in serum lutein as compared to baseline

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Li *et al.* 2010 (*55*)	40 healthy adults	12 mg FloraGLO/day for 4 months	Significant increase in serum lutein as compared to baseline
Norkus *et al.* 2010 (*79*)	36 healthy adults	12.2 mg FloraGLO/day for 4 weeks	Significant increase in serum lutein as compared to lutein esters
Romagnoli *et al.* 2010 (*56*)	10 preterm infants	0.5 mg/kg body weight (one dose)	Increase in serum lutein as compared to baseline (statistics not run)
Nakagawa *et al.* 2009 (*57*)	6 healthy adults	9.67 mg FloraGLO/day for 4 weeks	Significant increase in serum lutein as compared to baseline
Johnson *et al.* 2008 (*43*)	25 healthy older women	12 mg FloraGLO/day for 4 months	Significant increase in serum lutein as compared to baseline
Schalch *et al.* 2007 (*45*)	37 healthy adults	10 mg FloraGLO/day for 6 months followed by 20 mg FloraGLO/day for additional 6 months or 10 mg FloraGLO/day and 10 mg zeaxanthin/day for 6-12 months	Significant increase in serum lutein as compared to placebo
Franciose *et al.* 2006 (*46*)	32 healthy adults	4-6 mg FloraGLO/day for 12 weeks	Significant increase in serum lutein as compared to baseline
Khachik *et al.* 2006 (*59*)	45 healthy adults	2.5, 5, 10 mg FloraGLO per day for 6 months	Significant increase in serum lutein as compared to baseline
Tanumihardjo *et al.* 2005 (*60*)	9 healthy adults	18 mg FloraGLO/day in one dose	Increase in mean serum lutein following supplementation (statistics not run on magnitude of increase)
Thurmann *et al.* 2005 (*61*)	16 healthy adults	4.1 mg or 20.5 mg FloraGLO/day for 42 days	Significant increase in serum lutein as compared to baseline
Molldrem *et al.* 2004 (*62*)	9 healthy adults	1.7 mg FloraGLO/day for 7 days	Significant increase in serum lutein as compared to baseline
Cardinault *et al.* 2003 (*48*)	12 healthy young and 17 healthy elderly	9 mg FloraGLO/day for 5 weeks	Significant increase in serum lutein as compared to baseline
Bowen *et al.* 2002 (*63*)	18 healthy adults	20.7 or 24.5 mg FloraGLO/day in one dose	Significant increase in serum lutein as compared to baseline
Castenmiller *et al.* 1999 (*93*)	12 healthy adults	6.6 mg FloraGLO/day for 3 weeks	Significant increase in serum lutein as compared to baseline
van het Hof *et al.* 1999 (*94*)	10 healthy adults	9 mg FloraGLO/day for 4 weeks	Significant increase in serum lutein as compared to baseline and placebo
Riedl et al. 1999 (*90*)	6 healthy women	0.4 mg/kg body weight (single dose) served with a meal containing different types of dietary fiber	Bioavailability of lutein as measured by plasma lutein levels was significantly reduced by dietary fibers
Kostic *et al.* 1995 (*64*)	8 healthy adults	0.5 mmol/kg body weight FloraGLO/day in one dose	Significant increase in serum lutein as compared to baseline

[a]Only subjects who received FloraGLO supplementation are listed. [b]Only FloraGLO dose is listed. Trial may have included other nutrients.
[c]Statistical significance defined as $p < 0.05$. Publications reporting significant results are reported in blue.

Table 10. Short-Term Marker of Lutein Intake, Serum/Plasma Lutein in Subjects with Ocular Diseases

Trial	Cohort[a]	Protocol[b]	Effect on Serum Lutein Level[c]
Wolf-Schnurrbusch *et al.* 2015 (*85*)	79 patients with AMD	10 mg FloraGLO for 6 months	Significant increase in serum lutein as compared to baseline
Akuffo *et al. 2015 (37)*	13 AMD patients	20 mg FloraGLO and 0.86 mg zeaxanthin/day for 3 weeks	Significant increase in serum lutein as compared to baseline

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AREDS 2, 2013 (*18*)	2107 adults (age 50-85)	10 mg FloraGLO and 2 mg zeaxanthin/day for 5 years	Significant increase in serum lutein as compared to baseline and placebo
Arnold *et al.* 2013 (*39*)	104 AMD patients	10 mg FloraGLO and 1 mg zeaxanthin/day or 20 mg FloraGLO and 2 mg zeaxanthin/day for 12 months	Significant increase in serum lutein levels at both doses as compared to baseline
Meagher *et al.* 2013 (*53*)	11 healthy adults and 10 AMD patients	20 mg FloraGLO and 2 mg zeaxanthin/day for 8 weeks	Significant increase in serum lutein as compared to baseline
Berson *et al.* 2010 (*26*)	110 retinitis pigmentosa patients	12 mg FloraGLO/day for 4 years	Significant increase in serum lutein as compared to baseline
Huang *et al.* 2008 (*58*)	21 AMD patients and 19 healthy adults	10 mg FloraGLO/day and 2 mg zeaxanthin/day for 6 months	Significant increase in serum lutein as compared to baseline
Aleman *et al.* 2007 (*29*)	8 Stargardt disease and 3 cone–rod dystrophy patients	20 mg FloraGLO/day for 6 months	Significant increase in serum lutein as compared to baseline
Duncan *et al.* 2002 (*49*)	7 choroideremia (form of retinal degeneration) patients	20 mg FloraGLO/day for 6 months	Significant increase in serum lutein as compared to baseline
Aleman *et al.* 2001 (*35*)	23 patients with retinal degeneration and 8 healthy subjects	20 mg FloraGLO/day for 6 months	Significant increase in serum lutein as compared to baseline

[a]Only subjects who received FloraGLO supplementation are listed. [b]Only FloraGLO dose is listed. Trial may have included other nutrients.
[c]Statistical significance defined as $p < 0.05$. Publications reporting significant results are reported in blue.

MISCELLANEOUS

Table 11. FloraGLO Lutein Supplementation on Other Health-Related Outcomes

Trial	Cohort[a]	Protocol[b]	Outcome[c]
Hayashi *et al.* 2012 (*92*)	13 patients undergone bilateral cataract surgery	6 mg FloraGLO/day for 6 weeks following surgery	Expression levels of glucose-6-phosphate dehydrogenase and 18S RNA in anterior tissues from the eye were significantly higher after supplementation
Teixeira *et al.* 2009 (*91*)	10 healthy athletes	2 mg FloraGLO/day for 4 weeks	Exercise induced increase in cortisol level was significantly lower following supplementation
Nakagawa *et al.* 2009 (*57*)	6 healthy adults	9.67 mg FloraGLO/day for 4 weeks	Erythrocyte lutein concentration increased and erythrocyte phospholipid hydroperoxides decreased significantly from baseline
Reboul et al. 2007 (*88*)	8 healthy men	18 or 36 mg FloraGLO (single dose) served with a meal	No significant difference in postprandial plasma chylomicron triacylglycerol and tocopherol responses between two lutein doses
Reboul et al, 2007 (*89*)	8 healthy men	18 mg FloraGLO with or without other antioxidants (single dose) served with a meal	No significant difference in postprandial plasma chylomicron-rich fraction triacylglycerol responses following ingestions of the two meals
Hoffmann et al. 1999 (*12*)	6 healthy women	0.4 mg/kg body weight (single dose) served with a meal	No significant effect on postprandial cholesterol and triacylglycerol concentrations

[a]Only subjects who received FloraGLO supplementation are listed. [b]Only FloraGLO dose is listed. Trial may have included other nutrients.
[c]Statistical significance defined as $p < 0.05$. Publications reporting significant results are reported in blue.

CONCLUSIONS

By its very nature, the global vitamin and dietary supplement market relies upon clinical evidence in order to differentiate their products in the marketplace. "Science-backed, not science borrowed" is more than a just slogan for FloraGLO Lutein. Many lutein brands borrow the science of FloraGLO Lutein to substantiate the health benefits for their lutein ingredients. Therefore, it is good business sense to use FloraGLO Lutein, the brand shown to actually provide these differentiating and important health benefits. It is no wonder that FloraGLO is the lutein brand chosen by leading scientists and researchers

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for their clinical work, including NEI's AREDS2 – the largest lutein supplementation trial to date. You should definitely consider making the same choice. FloraGLO Lutein – the most clinically researched lutein brand worldwide.

AKNOWLEDGEMENTS

We thank Diane Alexander, Ph.D., Tatania Emmick and Christine Emilien, Ph.D. for their contrition to earlier versions of this technical literature.

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Note: References #11-98 are the list of published clinical trials of FloraGLO from PubMed as of November 1st, 2017.

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