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Palm Nutraceutical Excellence

EVNol SupraBio™

20 YEARS OF BRAIN HEALTH RESEARCH AND BEYOND
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Vitamin E is vital for overall wellness in general. Interestingly, more and more research have proven that Vitamin E has even more to offer. Vitamin E is composed of eight different compounds or isoforms - four tocopherols and four tocotrienols. Research has examined the role of tocopherol in human health, but new scientific evidence shows that tocotrienol offer unique health benefits that tocopherol alone may not provide. One of the unique benefits is in brain health and neuroprotection at minute nanomolar concentration.

However, in order to confer the optimal health benefits especially in the brain, tocotrienol has to accumulate at targeted tissues to reach therapeutic level at the shortest possible time. Yet, like most fat-soluble phytonutrients, tocotrienol from a regular oil extract is poorly absorbed and exhibit poor bioavailability. Therefore, it is unfortunate that most of the tocotrienol is being passed out from the body, rendering it "ineffective" erroneously.

**EVNol SupraBio™ System** is a patented, bio-enhanced self-emulsifying oral delivery system that provides a consistent and improves oral absorption of each individual tocotrienol isoforms by up to 300%, compared to regular tocotrienol oil extract.

**EVNol SupraBio™** is a natural full spectrum palm tocotrienol and tocopherol complex - the only branded and patented natural ingredient that provides the synergistic benefits of tocotrienol complex and vitamin E activity from alpha-tocopherol.

This whitepaper will take you on a journey to discover the unique brain health benefits and neuroprotection research of **EVNol SupraBio™**, that began 20 years ago, solidifying it as one of the most potent neuroprotective phytonutrients in the market.
Consisting of 8 different isoforms namely, alpha-, beta-, gamma- and delta-tocopherol as well as alpha-, beta-, gamma- and delta-tocotrienol, Vitamin E has long been known to have tremendous health benefits. The early research on Vitamin E started with alpha-tocopherol since it was the first to be discovered in 1922. In the Year 2000 and beyond, a significant body of scientific evidence began to emerge that shows that tocotrienol possesses a wide array of unique health benefits, which are, quite surprisingly, not seen with the regular tocopherol vitamin E! One of these unique health benefits is in brain health and neuroprotection at minute level (nanomolar concentration) in the brain.

The first neuroprotective properties of palm tocotrienol (EVNol™) were discovered in the year 2000. In this research, led by the renowned, Professor Chandan Sen (then with Ohio State University Wexner Medical Center), he and his colleagues showed that alpha tocotrienol, at extremely low concentration (nanomolar, $10^{-9}$), was able to modulate glutamate toxicity [5]. In a
healthy brain, glutamate is released when it is needed to convey signals between one neuron and another. However, during a brain injury or trauma such as stroke or concussion, a sudden surge of glutamate occurs which leads to a cascade of neuronal cell death (apoptosis) that eventually affect brain function and brain damage. Interestingly, this nanomolar level of alpha-tocotrienol promoted complete recovery of neuron even when it was introduced several hours after glutamate toxicity. What makes it even more interesting is that, this effect was not observed with the regular tocopherol form of vitamin E. This significant scientific discovery marks the beginning of the research on tocotrienols in neuroprotection, especially against stroke-induced injuries and steered the direction of tocotrienol vitamin E in brain health research, for the past 20 years.

While it is exciting to discover palm tocotrienol complex's unique neuroprotective properties, there is one significant issue that many generic tocotrienol producers (and other phytonutrient producers) in the market have overlooked. The issue is bioavailability! But why is bioavailability of a phytonutrient important?
In a layman’s term, bioavailability is used to convey the fact that not 100% of a particular nutrient or ingredient you consume will be absorbed, regardless whether the nutrients are in the form of food or supplements. Macronutrients like carbohydrates, proteins, and fats usually have high bioavailability. On the other hand, micronutrients like vitamins and minerals have poor bioavailability. To make thing worse, their bioavailability can vary depending on many factors such as human’s body condition, fat intake, route of delivery, and many more.

Similar to the commonly found tocopherol, tocotrienol has poor bioavailability and low absorption. In fact, the absolute oral bioavailability of alpha-, gamma- and delta-tocotrienol has been reported to be low and erratic, at 27.7%, 9.1%, and 8.5% respectively [2].
The poor bioavailability and low absorption may hinder the tocotrienol from being absorbed and utilized in the body. This is because, bioavailability is the key in term of nourishment and efficacy as it ensures that your body gets the nutrients it deserves from the food or supplement that you take daily.

In addition to confirming that you are not wasting your precious tocotrienol, consuming a tocotrienol with high bioavailability gives the assurance that it is being absorbed into the bloodstream (plasma), as the first phase of its journey to conferring the health benefits associated with tocotrienol.

Once the tocotrienol is in the bloodstream, the tocotrienol must be transported to the targeted organs and tissues in order for it to penetrate the cells. This is known as bioefficiency.

Not to mention, in the case of brain injury, the bioavailability of the tocotrienol has to be robust enough that it could be transported (crosses the blood-brain barrier) and accumulated in the brain for efficacy. For that reason, the formulation of tocotrienol with enhanced bioavailability and proven bioefficiency in dietary supplements or functional foods and beverages, are highly recommended for bioefficacy. In addition, using scientifically-substantiated (bioefficacy) tocotrienol is of utmost importance to ensure that one gets the intended health benefits. Hence, the 3 B's in tocotrienol formulation.

**EVNol SupraBio™** is the only branded tocotrienol complex in the market that provides these 3 B's in a formulation.
Realising the potent neuroprotective properties of tocotrienol and the significant benefits of increased bioavailability and bioefficiency (higher absorption and proven accumulation in vital human organs), ExcelVite together with Hovid Berhad, embarked on an extensive research to develop the SupraBio™ System – a patented self-emulsifying delivery system for EVNol™ (Standard Tocotrienol Oil Extract) that ensures enhanced and consistent absorption of each individual tocotrienol isoforms into human plasma by up to 300% compared to a standard tocotrienol oil extract [3].

EVNol SupraBio™ contains a self-emulsifying delivery system (SEDS) - a mixture of oil and FDA-approved food emulsifiers at an optimum ratio that will self-emulsify in the gastrointestinal tract. The emulsion will then undergo lipolysis to form small particles of colloidal dimensions, mimicking the intraluminal processing, which is a critical action for optimal absorption of tocotrienol. Thus, the absorption of tocotrienol is not only being enhanced and maximized but more importantly, allowing one to achieve therapeutic plasma level at a lower supplementation dosage, to achieve the
proven unique health benefits of tocotrienols. It is also worth to note that EVNol SupraBio™ is the only tocotrienol complex in the market to have an actual human tissue distribution study, where the tocotrienol from EVNol SupraBio™ are proven to be significantly absorbed and accumulated in vital human organs especially the brain and heart. 

In summary, EVNol SupraBio™ possesses the following unique attributes and properties:

1. An average of 250% increase in absorption (2 period, 2 sequence crossover human study). Hence achieving therapeutic level at lower dosage of supplementation.
2. Consistent & Rapid absorption
3. Promotes absorption of tocotrienols via lymphatic system as well.
4. Does not depend on dietary fat intake / food
5. Ensures a rapid transport of tocotrienols into the blood. Faster to reach maximum peak
6. It is the ONLY tocotrienol formulation that have actual human tissue distribution data / study
7. The most clinically-researched tocotrienol in the market
8. Branded-Ingredient (Not Generic Tocotrienol)
As a result of the successful development of the patented and bioenhanced EVNol SupraBio™, the neuroprotection research of tocotrienols continues with using this branded tocotrienol ingredient, for its higher bioavailability and bioefficiency properties.

The science and research of EVNol SupraBio™ in brain health and neuroprotection began in 2000 - a 20-year journey of meticulous research including mechanistic studies.
Brain trauma (stroke, concussion, trauma) results in release of excessive glutamate that leads to neuronal cell death (apoptosis). Nanomolar ($10^{-9}$) level of alpha-tocotrienol promotes complete recovery of the affected neurons. What was even amazing is that the neurons recovered when alpha-tocotrienol was introduced several hours after glutamate-induced injury. [5]

A series of mechanistic in-vitro study, funded by the United States’ National Institutes Health (NIH) was conducted. These studies revealed that EVNol™ modulate 5 key cytosolic targets that are involved in regulating neuronal cell death or survival:

- Reduction in c-Src kinase activation [30]
- Inhibition of 12-lipoxygenase phosphorylation [31]
- Inhibition of phospholipase A2 (PLA2) [32]
- Up-regulation of Multidrug resistance-associated protein I (MRP1) [33]
- Inhibition of 12-LOX activity to preserve miR29b (neuronal survival factor) [34]

A pre-clinical study on large animal model shows that supplementation of EVNol SupraBio™ daily for 10 weeks results in a significant 20 - 40% reduction in stroke-induced infarct volume in the brain. Additionally, EVNol SupraBio™-supplemented animal also demonstrated higher relative connectivity of white matter fiber tracts, improved cerebrovascular collateral circulation and increased expression of pro-arteriogenic genes (formation of new blood vessels around the infarct area). [11]
A ground-breaking human tissue distribution study, funded by US’ National Institute of Health, with EVNol SupraBio™, conclusively proves that tocotrienols from EVNol SupraBio™ are highly bioavailable and accumulates in vital human organs including the brain, heart, liver and skin. This is very significant and paramount because it was the first and the only human tissue distribution study ever conducted with a tocotrienol ingredient or product.

A double-blind, placebo-controlled clinical study on the effect of EVNol SupraBio™ on White Matter Lesions, was carried out by a group of researchers from the School of Pharmaceutical Science, University Science of Malaysia. White Matter Lesions (WML’s) are abnormal hyperintense region that occurs in the brain, as one ages. A systematic review of 46 published studies and meta-analysis shows that the presence of WML’s increases the risk of stroke and dementia (29).

In this clinical study, 121 MRI (Magnetic Resonance Imaging)- confirmed WML subjects received either EVNol SupraBio™ or placebo for 24 months.

The results show that the lesion size of the control group continues to grow and become more severe; whereas supplementation of EVNol SupraBio™ attenuates the progression of WML and thereby protects the brain from neurodegenerative conditions and which will eventually lead to the maintenance of a healthy brain and cognitive functions.

2014

Ongoing Phase II Clinical Trial [13]-
NUTRITION: Natural Tocotrienol against Ischemic Stroke Event, Clinical Trial Number NCT01578629.
In summary, the vigorous research conducted for the past 20 years, has built EVNol SupraBio™ into a perfect ingredient for brain health and neuroprotection.

In fact, it has reached to the pinnacle stage of its neuroprotective effect, where :-

1) Mechanistic Studies - The neuroprotective mechanism of EVNol SupraBio™ has been elucidated and published.
2) Bioavailability - The pharmacokinetics and enhanced absorption of tocotrienols from EVNol SupraBio™, into the human blood plasma has been studied and published.
3) Bioefficiency - The delivery and accumulation of tocotrienols from EVNol SupraBio™, into the human brain has been studied and published as well.
4) Bioefficacy (Clinically-Researched) - EVNol SupraBio™ is the only branded tocotrienol ingredient with the most published human clinical studies.

In terms of cognitive support, four large epidemiological studies conducted by researchers in Europe show that Vitamin E Complete (full spectrum tocotrienols and tocopherols) reduces the risk of mild cognitive impairment (MCI) and Alzheimer’s disease (AD) in elderly Europeans. When compared to cognitively-normal people, AD and MCI subjects demonstrated significantly lower levels of total tocotrienol, total tocopherol, and total vitamin E. Hence, low plasma tocotrienol and tocopherol are strongly linked to AD and MCI, with tocotrienol having a stronger inverse correlation compared to tocopherol [14-17].

Not ALL Tocotrienol Formulations are Created Equal

There are other tocotrienol ingredients and products in the market. However, none of these generic tocotrienol products could offer the same 3 B’s properties (Bioavailability, Bioefficiency and Biofficacy) posses by EVNol SupraBio® and that has the backing of 20 years of meticulous research in brain health and neuroprotection.
Beyond Neuroprotection

Other Unique Health Benefits of EVNol SupraBio™

The unique health benefits of EVNol SupraBio™ is not limited to neuroprotection. While the regular tocotrienol oil extract is still grappling with the issue of poor bioavailability and low absorption, EVNol SupraBio™ has been the subject of most clinical studies demonstrating the diverse area of health benefits of tocotrienol. Almost all the human clinical studies with EVNol SupraBio™ are based on the gold standard - double-blind, placebo-controlled protocol with supervision from renowned researchers and experts worldwide. In addition to the countless number of in-vitro and pre-clinical animal studies, these published human clinical studies have substantiated the unique health benefits of EVNol SupraBio™, underscoring it as a potent form of natural ingredient and the most potent form of vitamin E, for brain health / neuroprotection.

A significant number of human clinical studies have shown that EVNol SupraBio™ has unique protective effects in terms of heart health, liver health, skin nutrition and most recently in supporting diabetes care via attenuation of diabetic complications. EVNol SupraBio™ has also been shown to promote hair growth in alopecia subjects.
Promoting Healthy Heart

According to the Centre for Disease Control and Prevention (CDC), an estimated 85.6 million American adults (>1 in 3) have 1 or more types of cardiovascular disease (CVD). Of these, 43.7 million (more than half of the affected population) are estimated to be ≥60 years of age [18]. On the other hand, CVD remains the leading cause of mortality and a major cause of morbidity in Europe, as reported by European Cardiovascular Disease Statistics 2017 European Heart Network [19].

A clinical study on hypercholesterolemic subjects has shown that supplementation with EVNol SupraBio™ significantly reduced total cholesterol and LDL-Cholesterol on the 4th month of supplementation [20]. Meanwhile, another study on healthy subjects demonstrated a trend towards arterial compliance enhancement after 2 months supplementation of EVNol SupraBio™ [21]. Collectively, these clinical studies together with the myriad of in-vitro studies have proven the effectiveness of EVNol SupraBio™ in supporting heart health.

Promoting Healthy Liver Function

Liver is the second largest organ in the body. The principal roles of the liver include removing toxins from the body, processing food nutrients and regulating body metabolism. Unfortunately, according to the American Liver Foundation, up to 25% of US population are living with fatty liver, which is the accumulation of fat in the liver for more than 5-10% of its weight [22]. Compounding the issue is that fatty liver is a silent condition or asymptomatic. As a result, a huge percentage of the population would not even realized that they have fatty liver unless they have an abdominal ultrasound scan. Fatty liver has been known to be a precursor to the 3 main metabolic syndrome diseases - obesity, hypertension and diabetes. It is the common thread that runs through all these 3 diseases.

In an attempt to address this silent killer, two human clinical studies were conducted on subjects with fatty liver. In the first study (a double-blind and placebo-controlled study) on non-alcoholic fatty liver, supplementation with EVNol SupraBio™ significantly attenuates fatty liver in over 50% of the supplemented group [23]. In the second study, EVNol SupraBio™ improves liver stiffness in subjects that lead a healthy lifestyle and thereby promotes healthy liver function.
Diabetes is a growing public health burden. A long-term elevated blood sugar level will damage your kidney. Diabetic nephropathy (diabetic kidney disease) is now the leading cause of chronic kidney disease in the U.S.

In the U.S., diabetic nephropathy accounts for about 40% of new cases of end-stage renal disease. Diabetic nephropathy is a common complication of diabetes, Types 1 and 2.

More than 100 million U.S. adults are now living with diabetes or prediabetes, according to a new report released today by the Centers for Disease Control and Prevention (CDC). The report finds that as of 2015, 30.3 million Americans – 9.4 percent of the U.S. population – have diabetes.

Over time the high blood sugar associated with untreated diabetes causes high blood pressure. This in turn damages the kidneys by increasing the pressure in the delicate filtering system of the kidneys.

In a randomized, double-blind, placebo-controlled study, supplementation of EVNol SupraBio™ for 2 months has significantly reduced serum creatinine compared to placebo in subjects with diabetic nephropathy. This result suggests that EVNol SupraBio™ prevented the progression of kidney impairment by stabilizing serum creatinine.

Preliminary result from an ongoing Phase IIB study shows the memory effect of EVNol SupraBio™ in reducing serum creatinine level.

In another interesting study (the largest tocotrienol human clinical study published to date), shows that daily dose of EVNol SupraBio™ reduces lancinating pain (severe knife-cut feeling of pain) one of the debilitating symptoms, in diabetic neuropathy (DNP) patients.
Promoting Hair Growth

As we age, we expect to not only live a quality life by aging healthily but also to age beautifully. In the elderly, as the hairs spend more time in the last telogen cycle, it results in shedding of hair faster than in growing it back. A randomized, double-blind, and placebo-controlled clinical trial conducted at the School of Pharmaceutical Sciences, University of Science Malaysia, shows that oral supplementation with EVNol SupraBio™ could help in promoting hair growth in men and women who suffer from hair loss [27]. The promotion of hair growth by tocotrienols is also supported by an animal study (2017) where topical application of EVNol SupraBio™ promotes hair growth in shaved skin of diabetic mice. This study remarkably elucidated a novel mechanism of how EVNol SupraBio™ promotes the growth of new hairs.

The preferential accumulation of tocotrienols at the stratum corneum/skin is another factor that contributes to this effect as well [4]. EVNol SupraBio™'s effect on promoting new hair growth has been awarded a US Patent (U.S Patent No: 7,211,274).
Brain Health / Neuroprotection

- 200mg of EVNol SupraBio™, twice daily for 10 weeks may reduce brain tissue damage post-stroke in a preclinical setting [11].

- 200mg of EVNol SupraBio™, twice daily for 24 months reduces stroke risk via attenuation of white matter lesion (pre-stroke) [12].

Promotes Hair Growth

- 50mg of EVNol SupraBio™, twice daily for 32 weeks shows a gradual mean increase (34.5%) in hair numbers [27].

- All volunteers in the EVNol SupraBio™ group recorded an increase in the number of hairs in the evaluation area, with 64% volunteers showed hair regrowth of between 10 - 35% (US Patent Number 7,211,274).

Promotes Healthy Heart

- 150mg EVNol SupraBio™, twice daily for 6 months, significantly reduces total cholesterol and LDL cholesterol after only 4 months of supplementation [20].

- A trend towards arterial compliance enhancement was observed after 2 months supplementation of either 50mg, 100mg and 200mg of EVNol SupraBio™, twice daily [21].

Promotes Healthy Liver Function

- 66.7% patients in the EVNol SupraBio™ group show significant improvement in fatty liver condition [21].

- 100mg EVNol SupraBio™ (twice daily) + positive lifestyle intervention is about 4 times more effective in ameliorating liver stiffness compared to lifestyle modification alone [20].

- EVNol SupraBio™ shows efficacy in improving MELD scores among end stage liver disease patients [4].

Attenuates Diabetic Complications

- 2 months supplementation of tocotrienol (EVNol SupraBio™) significantly reduces serum creatinine (biomarker for kidney damage) in diabetic nephropathy patients [25].

- Tocotrienol (EVNol SupraBio™) helps in managing lancinating pain among diabetic peripheral neuropathy patients [26].
With the variety of phytonutrients available in the market for brain health / neuroprotection, manufacturers and formulators of dietary supplement and functional foods/drinks, might be spoilt for choices. Therefore, it is important to bear in mind that it is best to formulate a product that caters to and meet the market’s as well as consumers’ demand. The public nowadays strongly advocates transparency and will support a certain brand fervently if it aligns with their values. In addition, they also demand products formulated with branded natural ingredients that have been studied extensively (clinically - substantiated).

**Conclusion**

**EVNol SupraBio™** meets all these important criteria in new product development for brain health and neuroprotection.

**EVNol SupraBio™** is extracted from sustainably-produced crude red palm oil from plantations within Peninsular Malaysia and being processed in the only PIC/S-cGMP (pharmaceutical standards) tocotrienol facility in the world – placing **EVNol SupraBio™** at the pinnacle in term of tocotrienol quality.

**EVNol SupraBio™** is verified Non-GMO by the US Non-GMO project. It is also Kosher- and Halal-certified.
Besides being scientifically-substantiated and of the highest quality, the most important factor that differentiates EVNol SupraBio™ from other generic tocotrienol ingredient in the market is its 3 B’s properties.

In view of the poor and low bioavailability of tocotrienols, it is of utmost importance to choose the right bioenhanced tocotrienol system that is EVNol SupraBio™ - not just because of its strong and broad body of scientific evidence (Bioefficacy), but also for its assured enhanced absorption of each individual tocotrienol isoforms into the plasma (Bioavailability) and delivery as well as accumulation in the brain and other vital human organs for optimum benefits and functions (Bioefficiency).

The Unique Selling Points of EVNol SupraBio™ are: Bioavailability, Bioefficiency and Bioefficacy (3 B’s)

- **EVNol SupraBio™** is the one and only 2nd generation of tocotrienol complex product in the market. Its patented and bio-enhanced full spectrum tocotrienol complex allows for consistent and an improved absorption of each individual tocotrienols by up to 300% higher than any tocotrienol oil extract. Hence achieving therapeutic level in bloodstream or higher blood level at the same dosage of supplementation.
- Consistent & rapid absorption
- Promotes absorption of tocotrienols via lymphatic system as well.
- Does not depend on dietary fat intake / food
- Ensures a rapid transport of tocotrienols into the blood. Faster to reach maximum peak
- Clinically-Substantiation - Almost all the tocotrienol human clinical studies in the past 10 – 15 years have been carried out with our EVNol SupraBio™ (bioefficacy).
- It is the ONLY tocotrienol formulation that have actual human tissue distribution data / study (published in J of Nutrition, 2012). Hence, guaranteed bioavailability (absorption into blood plasma) and bioefficiency (accumulation into vital human organs).
- The most bioavailable tocotrienol product in the market with 3B’s – Bioavailability, Bioefficiency and Bioefficacy
- It is 100% Non-GMO and Non-Soy and reflects the latest science on vitamin E – unique health benefits of d-mixed tocotrienols (Super vitamin E)

The applications are widespread ranging from aging to other neurodegenerative disorders that represent a sizeable fraction of all health problems taken together.

Tocotrienol content in our diet is trace at best. Hence, EVNol SupraBio™ -patented and bioenhanced natural full spectrum palm tocotrienol complex is well positioned to emerge as the most potent neuroprotective form of natural vitamin E.
References


ExcelVite manufactures these products under the tradenames -

- **EVNol™**
  - Natural Full Spectrum Tocotrienol/Tocopherol Complex

- **EVNol SupraBio™**
  - Patented and Bioenhanced Natural Full Spectrum Tocotrienol/Tocopherol Complex

- **EVTene™**
  - Natural Mixed-Carotene Complex

- **EVspectra™**
  - Natural Red Palm Oil Concentrate

- **EVRol™**
  - Natural Phytosterol Complex

ExcelVite Sdn. Bhd. is the first and largest PIC/S GMP-Certified producer of natural full spectrum palm tocotrienol complex, natural mixed carotene complex and phytosterol complex in the world.

**MALAYSIA (Factory and Headquarters)**

**ExcelVite Sdn. Bhd.**
Lot 56442, 7½ Mile, Jalan Ipoh/Chemor,
31200 Chemor, Perak, Malaysia.

Tel: +60 (05) 2014 192
info@excelvite.com
www.excelvite.com
www.tocotrienol.org
www.carotene.org

**AUSTRALIA**

+61 (03) 9801 3881
info@excelvite.com

Contact Person: Mr. Bryan See
klsee@excelvite.com

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