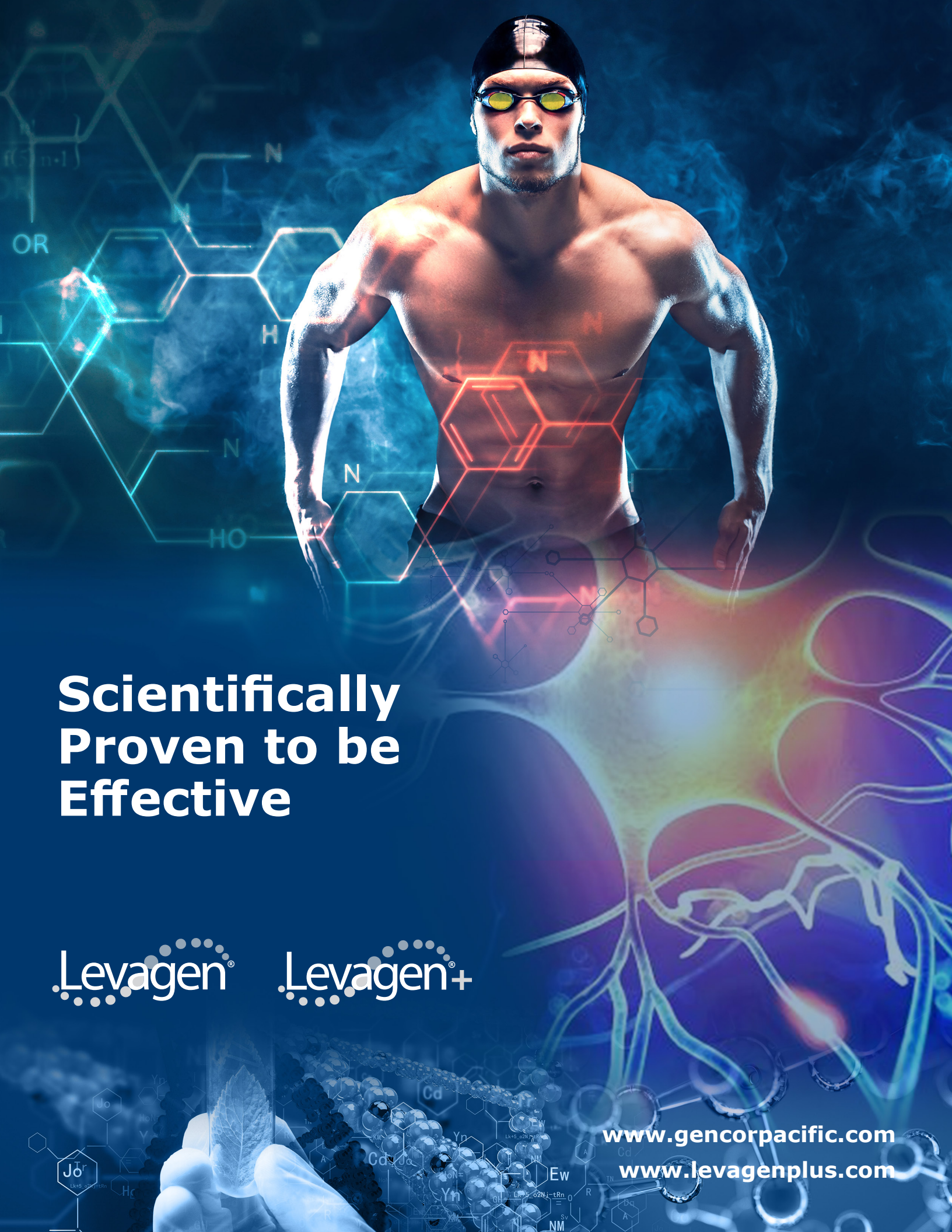

Scientifically
Proven to be
Effective
Levagen®
Levagen®+
www.gencorpacific.com
www.levagenplus.com

Levagen®

High Quality Palmitoylethanolamide (PEA)

Introducing Levagen®

Levagen® is high quality Palmitoylethanolamide (PEA). PEA is an endogenous endocannabinoid receptor agonist, a simple fatty acide amide, and originally a food component, commonly isolated from soybeans, peanuts, and egg yolks. PEA is also known to be naturally occurring in mammal tissues. It is produced as a biological response and repair mechanism, potentiating its actions at cannabinoid CB1, CB2 and GPR55 receptors, and TRPV1 channels. PEA is used for joint pain and sports inflammation. PEA can also contribute to relaxation and restfulness leading to a good quality of sleep.

Product benefits

The following structure-function claims for Levagen are provided here for informational purposes only and should be reviewed by your legal counsel prior to use in marketing materials, including product labels.

- Levagen® provides support for those with normal symptoms of mild to moderate osteoarthritis in the following ways:
  - Supports joint function*
  - Reduces joint stiffness*
  - Provides joint comfort*
- Supports restful sleep*
- Promotes falling asleep faster*
- Promotes feeling awake faster*
- Supports healthy inflammation response following normal exercise*
- Helps provide post exercise inflammation support*
- Provide efficacy on the recovery from muscle damaging exercise*
- Promotes immune health*
- Helps support overall immunity*

Science Inside

A double-blind, randomized, placebo-controlled study was conducted to demonstrate the safety and efficacy of Palmitoylethanolamide (PEA) (Levagen®) for the management of mild to moderate osteoarthritis symptoms.

The study was a 120 patient study with 40 patients on placebo, 40 patients on Levagen® 300 mg a day and 40 patients on Levagen 600 mg a day. 111 patients completed the study: 35 on Levagen 600 mg, 36 on Levagen® 300 mg and 40 on placebo.

The 300 mg dose was dosed 150 mg in the morning and 150 mg in the evening. The 600 mg was dosed 300 mg in the morning and 300 mg in the evening. The placebo was dosed once in the morning and once in the evening.

Both the 600 mg and the 300 mg doses were found to be statistically significant compared to the placebo on the:

- total WOMAC score
- pain subdomain
- stiffness subdomain
- function subdomain

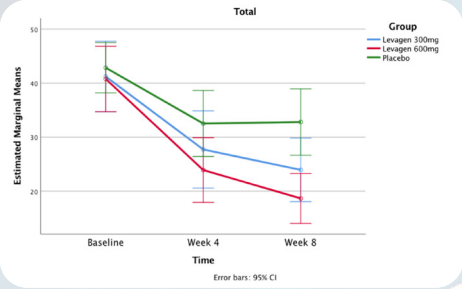


Figure 1. Total WOMAC score per treatment group

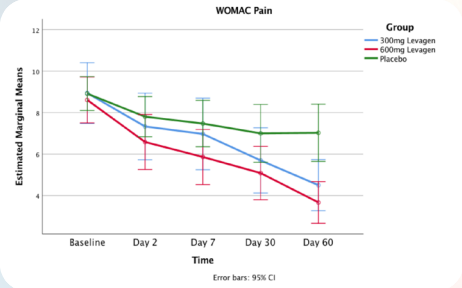


Figure 2. WOMAC pain score per treatment group

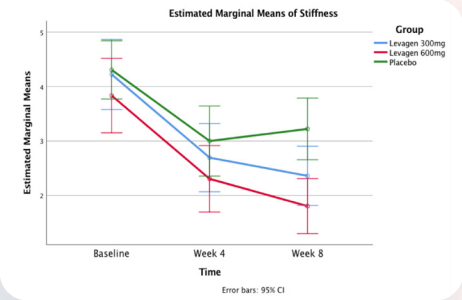


Figure 3. WOMAC stiffness score per treatment group

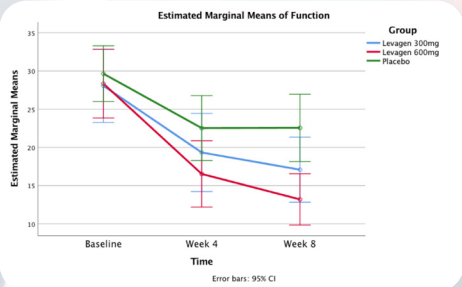


Figure 4. WOMAC function score per treatment group

* These statements have not been evaluated by the Food and Drug Administration.
This product is not intended to diagnose, treat, cure, or prevent any disease.

Levagen®+

High Quality PEA with LipiSperse

LipiSperse®

Introducing Levagen®+

Cold Water Dispersible Levagen | Powered by LipiSperse®

Levagen®+ is a cold water dispersible palmitoylethanolamide (PEA) powder, specifically designed to increase bioavailability. The product is powered by the LipiSperse® technology developed by Pharmako Biotechnologies, Australia.

In aqueous environments (such as the stomach), the specifically designed Levagen particles freely disperse. This net effect translates to increased bioavailability. With over 90% loading, this formulation supplies the largest amount of PEA in a water dispersible formulation.

Particle sizes are quality checked by Dynamic Light Scattering (DLS) analysis as well as Laser Light Obscuration.

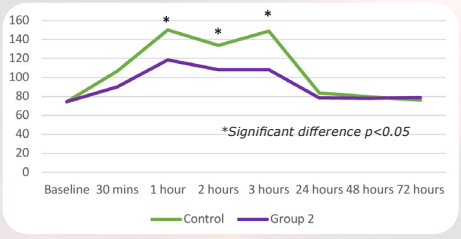


Figure 5. Myoglobin - Adjusted Means

There was a significant decrease in Myoglobin at 1,2, and 3 hours post exercise in the Levagen+ group

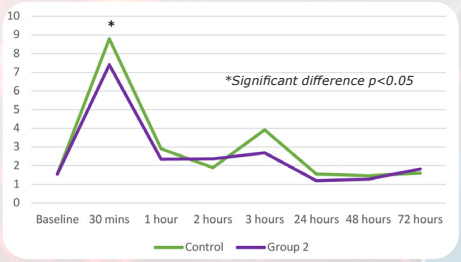


Figure 6. Lactate Scores

There was a significant difference in Lactate levels at each of the post exercise points, 30 minutes and three hours.

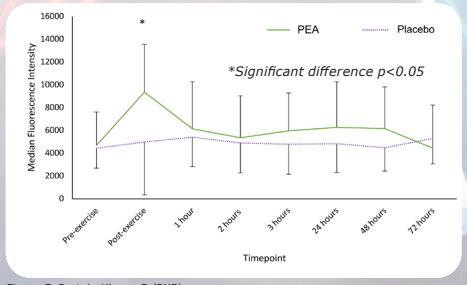


Figure 7. Protein Kinase B (PKB)

There was a difference in Mononuclear cell PKB (also known as Akt) median fluorescenceintensity in Levagen Plus post exercise.

Pharmacokinetic Study

A parallel, double-blind, bioavailability study to measure uptake of PEA over a 24-hour period. The objective of this trial was to determine whether the use of a Lipid-Based Drug Delivery System, LipiSperse®, can be successfully used to improve the bioavailability of Levagen.

The study was conducted with 28 healthy male and female volunteers over 18 years old. Participants were randomized into 2 groups (Levagen®+ or Standard PEA) with each group consuming a single 300mg dose of a PEA formulation. (Blood samples were taken at baseline and 30, 45, 60, 70, 90, 120, 180, 240 minutes post ingestion.)

Safety Analysis

Subjects were monitored and asked to report any possible side effects experienced as a result of PEA supplementation while at the research center.

Results

The primary outcome measure of the trial was the change in plasma uptake of PEA over a 4 hour period.

The Levagen®+ formulation significantly increased plasma PEA concentration above baseline concentrations by approximately 1.75 x that of the standard Levagen formulation.

These results indicate that by combining Levagen with the LipiSperse delivery system, PEA absorption is more effective than Levagen® alone, and it appears to mimic the human body's naturally occurring mixed miceller transport system for lipids

Exercise Recovery Study

A double-blind, randomized, clinical trial with a 72 hour treatment duration was conducted to measure the effect of 167.5mg of Levagen®+ on exercise recovery. The study was conducted with 28 healthy, recreationally-trained males aged 18 and 35 years old.

Muscle fatigue was induced using leg press and completion of 4 sets for as many repititions as possible, with 1 minute rest between sets. After muscle fatigue, blood parameters, VAS pain score, thigh circumference and questionnaires were completed.

Results

Levagen+ was shown to be statistically significant (when compared to the placebo) in:

- decreasing myoglobin levels post-exericse
- lower blood lactate concentration post-exercise
- increased protein kinase B (mTOR) levels associated with resistance training

Acute Joint Pain Study

2 week double-blind, randomized, placebo-controlled trial. 80 male and female participants

1. 350mg Levagen®+
2. Placebo

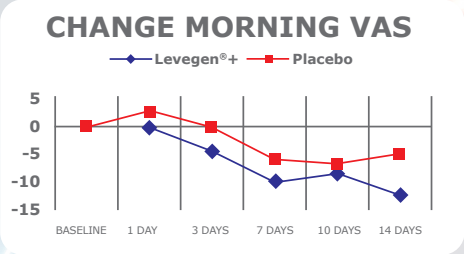
VAS score for pain

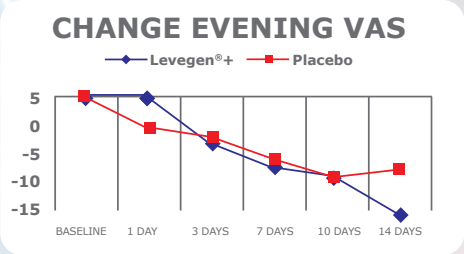
QOL (SF-36)

Results

Significant reduction in joint pain score after Day 3. This study demonstrates PEA's fast onset of action.

Improvement in QOL. Supports previous study re-effective on joint pain.





Headache Study

Double-blind, randomized controlled study. Levagen®+ compared to ibuprofen for reducing pain severity and duration of headaches.

International Classification of Headache Disorders 3rd Edition (ICHD3)

1. 525mg Levagen®+ (containing NLT 475mg PEA)
2. 400mg Ibuprofen

Headache pain (VAS) and GIT tolerance

Results

Levagen®+ was equivalent to Ibuprofen across the whole spectrum of headache resolutions.

Levagen®+ acted faster than Ibuprofen in resolving severe headaches.

These results may support use of Levagen®+ as a safe and effective alternative to treatments used for headaches.

Sleep Study

Double-blind, randomised controlled study. 350mg Levagen®+ (2 x 175mg PEA) taken orally with water one hour prior to sleep onset sleep quality and quantity as measured by the Pittsburgh Sleep Quality Index (PSQI) and wrist actigraphy. The PSQI completed at baseline, day 5, 2 weeks, 4 weeks, at supplementation completion (8 weeks) and at study completion Week 10.

The dose was 350 mg Levagen+ [Label Claim containing NLT 300 mg Palmitoylethanolamide], one hour prior to sleep onset.

Results

1.] Levagen®+ significantly reduced the time taken to sleep at night. The Levagen+ group reduced the time to get to sleep compared to placebo with statistically significant differences ($p<0.05$) measured from week 2 (10 minutes) continuing to reduce significantly at week 4 and 8 (16 and 19 minutes respectively) Figure 1.

2.] The amount of time to feel awake in the morning (sleep inertia) was statistically significant between the Levagen+ group and placebo group [$p<0.05$], with a decrease in time of approximately 11 minutes. So, the active group on Levagen+ woke up fresh in the morning, feeling fully awake faster.

3.] The Levagen®+ group had improved cognitive function on waking. This was statistically significant between active and placebo [$p<0.05$].

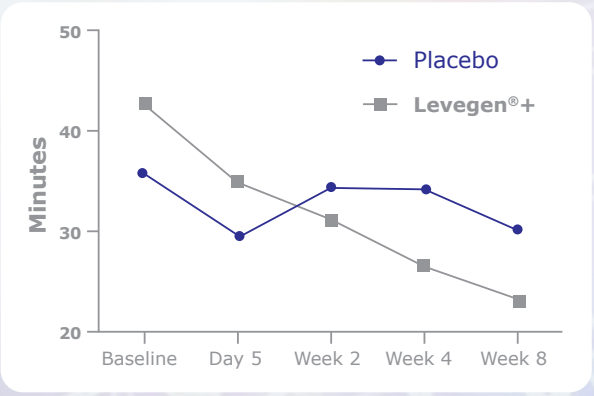


Figure 1. Sleep latency (time to get to sleep)

Gencor™
Lifestage Solutions

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info@gencorpacific.com

Version 2020_0728

* These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.