



**TAILORED
SOLUTIONS
FOR THE
FEMALE
ATHLETE**

GencorTM
Lifestage Solutions

COMMON CHALLENGES FEMALE

ATHLETES FACE IN SPORT

Women hold about \$72 trillion of all private wealth, which is 32% of the total wealth globally.¹ Women control \$43 trillion of global consumer spending², deeming the need for more female-centric focused strategies and products. Women are not only becoming increasingly wealthier, but they drive about 80% of all consumer purchasing, through a combination of their buying power and influence.³ While women drive the majority of consumer spending and make up about 50% of the human race, the culture of the business world, sports industry and sports nutrition market remains as macho-centric as ever.

Women are not only an economic force to be reckoned with, but over the past four decades, female participation in professional sports has skyrocketed to rival male participation numbers in the US⁴, and continues to make giant strides.

Women's participation in college athletics leapt more than 600%⁵ and women have been making more of an impact in Olympic competition and other male dominated sports like World Cup Soccer and Rugby as well as Wrestling, Bodybuilding and Basketball. Even though professional female athletes are still paid way less, land fewer endorsements and yield less airtime than their male counterparts, they continue to fight for the same support and recognition, and they are making their mark.

Women's sports have come a long way, which begs the question: why then, has the women's sports nutrition market not followed suit?

SHRINK IT AND PINK IT

Women are not a nutrition market to be ignored, but not enough effort goes into understanding, let alone formulating for the unique needs of athletic and active women, as goes into doing so for men.⁶ In fact only 2.5% of sports nutrition products are targeting women, in either marketing or formulation⁷ and their products tend to cost more per 100 grams⁸— Shrink It And Pink It!

The sports supplement segment, which dominated the sports nutrition market with a share of over 83.6%⁹ is missing the opportunity of developing a brand focused on female athletic consumers that is supported by science and speaks with the voice that female athletes want to hear.¹⁰

Nutraceutical brands need to truly understand the nutritional need of female athletes, the days of producing pink bottles of sparkly fat-burner with little to no help with performance are over. Companies need to create high-quality sports nutrition products for female athletes, formulas that will actually assist them with weight-lifting, endurance, recovery, post-workout regimes, and good overall health.

Studies applicable on men can't always be applied to women. Although many female athletes seek similar benefits and ingredients as their male counterparts, their end goals, dosages and nutritional needs can vary. Preferences also matter, as females are more likely to be pill-averse, seeking products that are indulgent yet affordable.

The sports nutrition industry lacks clinical research and product development specific to women, more quality and quantity of research needed, but awareness and innovation are stirring change. It is imperative for nutraceutical manufacturers to make sure that their formulations help the female athlete be the best she can be — minimize side effects and maximize performance.

WHY DO FEMALE ATHLETES REQUIRE SPECIAL ATTENTION OVER THEIR MALE COUNTERPARTS?

Hormones, hormones, hormones and much more!

Through the different stages of growth and maturity, women's nutritive need changes, the same stands true in case of pregnancy and post-pregnancy; lactation and the period of menopause.



Even in case of the regular menstrual cycle, women usually undergo a multitude of body changes that make all the difference in case of nutritive needs.

WHEN IT COMES TO SPORTS NUTRITION, WHAT ARE THE NUTRITIVE IMBALANCES THAT WOMEN FACE?

- Energy intakes usually don't match the requirement.
- Lower than required fat, protein and micro-nutrient intake, to meet the daily nutrition need.
- More fat-loss oriented diet.
- Ignorance toward carbohydrate consumption.
- Inadequacy of iron, calcium, vitamin B-12, and folate that in turn affects the red blood cell formation.

You see, this is where sports trainers and female athletes themselves need to focus on to ensure optimal performance and good overall health.

ADDRESSING IRON DEFICIENCY

Iron and calcium are two key nutrients that plummet in women with all the body changes throughout their lifetime.

Iron deficiency (ID), is the most prevalent micronutrient deficiency in the world:

- In the United States, ID with anemia (IDA) affects 3% to 5% of premenopausal women
- ID without anemia (IDNA) affects approximately 16% of premenopausal women¹¹
- Active women are twice as susceptible to IDNA^{12,13}
- 1 in 20 female athletes identified with anemia¹⁴
- 20-52% female athletes^{15,16}

Iron is an essential micronutrient involved in oxidative metabolism and critical to exercise performance. The prevalence of ID is much higher in active women for a variety of reasons, and poor iron status has been shown to be detrimental to overall health as well as physical performance.

Changes in oxidative metabolism and physical performance have been described in humans with compromised iron (Fe) status.¹⁷ ID was defined as Ferritin < 20 ng·mL. Serum ferritin (sFer) is the most common index of body Fe stores, reflecting Fe

stored in the liver. Low sFer in the setting of normal Hgb has been called nonanemic iron deficiency/IDNA/iron depletion, and has been reported in 16% to 57% of female athletes.

Beyond menstrual status, the increased prevalence of IDNA in active women may be due to one or a combination of the following factors: hemolysis (foot strike and impact);¹⁸ increased Fe losses (gastrointestinal tract, hematuria, and sweat);¹⁹ poor dietary Fe intake;^{20,21} or altered intestinal Fe absorption, including the effects of inflammation due to training.¹⁶

Other modifiable contributors to the prevalence of ID in this population may include routine use of nonsteroidal anti-inflammatory drugs, as well as blood donation.²²

OTHER RISKS OF IRON DEFICIENCY?

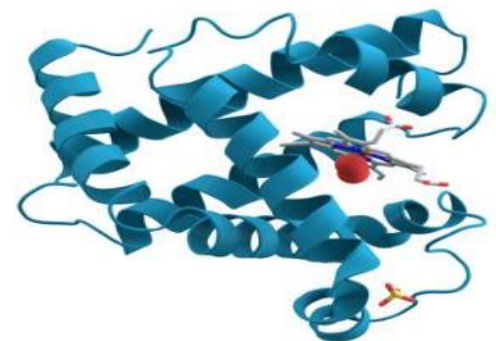
Iron is a major component of hemoglobin, a type of protein in red blood cells (RBC) that carries oxygen from your lungs to all parts of the body. Iron is a prooxidant, without enough iron, there aren't enough RBC to transport oxygen, which leads to

- Fatigue.
- Impaired cognitive and physical performance
- Shortness of breath
- Rapid heartbeat

Iron is also part of myoglobin, a protein that carries and stores oxygen specifically in muscle tissues.

- Extended recovery time post-exercise

Myoglobin is an iron- and oxygen-binding protein found in the muscle tissue



RISK OF OVERDOSE

- Toxicity
- Infection
- GI distress (constipation, upset stomach, nausea, vomiting, abdominal pain, diarrhea)

Toxicity is rare because the body regulates iron absorption and will absorb less if iron stores are adequate, a hereditary condition called hemochromatosis. Iron can build up in certain organs so that there is a higher risk of developing conditions like liver cirrhosis, liver cancer, or heart disease. Any of the effects of overloaded iron stores can and will impair athletic performance.²³

ATHLETES MOST AT RISK

- Weight-class based sports (i.e. wrestling, light weight rowing).
- Those emphasizing leanness (i.e. gymnastics, dance, cross-country).
- Endurance sports (i.e. Marathon runners, Tri-Athletes, Cyclist). **Runner's anemia**, is a specific condition that is common among long distance runners and can refer to one of three things: low iron, low hemoglobin, and low ferritin.

SOLUTION

Companies need to create high-quality sports nutrition products for female athletes, formulas that will actually assist them with weight-lifting, endurance, recovery, post-workout regimes, and good overall health. Specifically addressing the above mentioned issues the solution is HydroCurc®, a branded ingredient that is user centric and clinically researched and tested on both male and female subjects.

HYDROCURC®

HydroCurc® is the world's most bioavailable curcumin in a single dose, with potent anti-inflammatory and anti-oxidant properties utilizing the patented LipiSpense® delivery technology making it a cold-water dispersible powder.

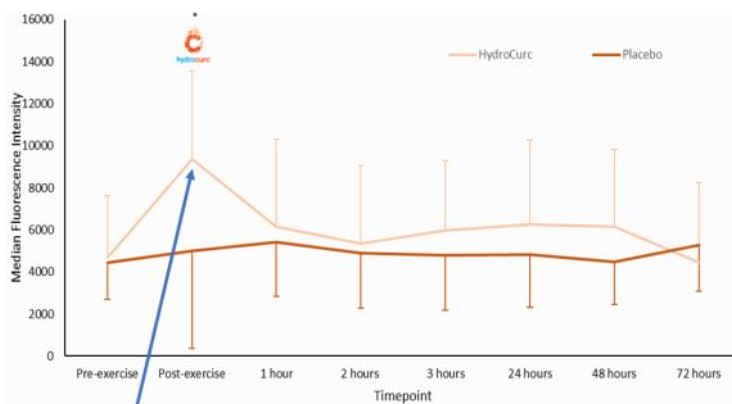
ESTABLISHED ROLE IN SPORT

According to the International Olympic Committee (IOC) consensus, one of the reasons athletes, female or male, often consume supplements is to gain a performance improvement indirectly from better recovery, optimizing composition, reducing risks of injury and illness, or to tolerate pain and soreness.²⁴ Beyond popular supplements such as creatine and omega-3s, curcumin has also been utilized for its anti-inflammatory benefits during the recovery process.

HydroCurc®, utilizes a unique LipiSpense® technology which provides for greater utilization. A

single dose of 750 mg HydroCurc® containing 85% curcuminoids produced peak plasma levels of 807 ng/ml³. This is well within the therapeutic range where curcuminoids can exert multiple anti-inflammatory effects.²⁵ A recently published study has also shown promising results for curcumin and sports recovery, demonstrating a significant reduction in delayed onset muscle soreness (DOMS) and thigh circumference (i.e. swelling) when supplementing with 500mg of HydroCurc®.²⁶ The increase in the anti-inflammatory marker IL-10 from supplementing with HydroCurc® could explain these outcomes. The same extract of curcumin also significantly reduced blood lactate levels, likely explaining why participants who consumed HydroCurc® were also able to maintain higher leg press power in the latter end of the exercise compared to placebo.

Furthermore, HydroCurc® activated the Akt/PKB signaling pathway – the downstream region of the mTOR pathway, suggesting its ability to optimize concurrent training responses (i.e. reduce soreness and increase muscle protein synthesis post-exercise). These findings indicated that the bioavailable curcumin may also allow for a quicker return to exercise training or a return to exercise training at higher thresholds.



FURTHER CLINICAL EVIDENCE: BDNF & FERRITIN STUDY

This 6-week, double blind, randomized, placebo-controlled study examined the effects of oral iron supplementation at low (18 mg) and high (65 mg) ferrous (FS) iron dosages, compared to a combination of these iron doses with a bioavailable formulated form of curcumin (HydroCurc®; 500 mg) on BDNF levels in a healthy adult cohort of 155 male (26.42 years ± 0.55) and female (25.82 years ± 0.54) participants.²⁷

Co-administration of a HydroCurc® with 18 mg elemental iron for 42 days can increase serum BDNF levels. Those with low ferritin levels may benefit from taking 500mg Hydrocurc® with 18mg iron by:

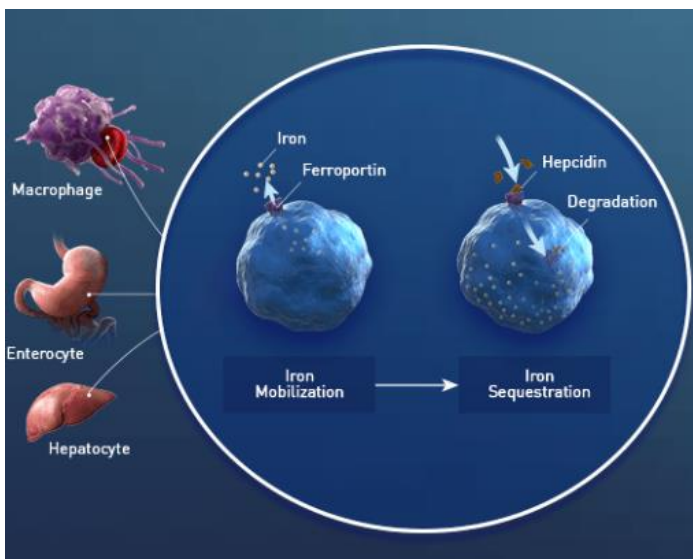
- Increasing serum BDNF levels in individuals
- Enhancing ferritin formation
- Correcting iron deficiency

As mentioned previously ID can lead to impaired cognition, among other issues. Previous studies have shown that independently, curcumin and iron are associated with improved BDNF levels. In the present study, co-administration was shown to result in increased serum BDNF levels.

Females with low ferritin levels may benefit from co-administering Hydrocurc® with iron:

- Increase serum BDNF levels
- Enhance ferritin formation
- Correct iron deficiency
- No adverse side effects (GI distress)

Hepcidin is a liver-derived hormone that serves as the key regulator of iron homeostasis in the body.²⁸ Hepcidin, a recently discovered peptide hormone, may play a significant role in iron regulation; chronic inflammation and exercise causes upregulation of hepcidin levels, leading to reduced iron availability and decreased intestinal absorption.²⁸



Source: <https://www.rethinkanemiaofckd.com/more-than-epo-and-iron.html>

Dose-dependent increase of elemental iron (105mg & 210mg) increased hemoglobin mass at high altitudes (increase ferritin = assimilated to RBC = more O₂) which is beneficial to the female athlete.

Factors influencing hepcidin:

- Chronic inflammation
- Exercise
- Iron intake
- EPO

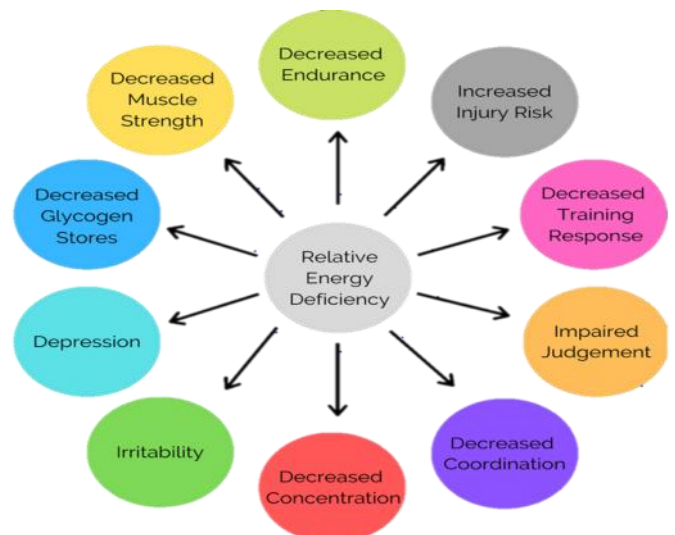
Thus during conditions where hepcidin is high, serum iron falls due to trapping within macrophages and liver cells and decreased gut iron absorption. Therefore, iron is unable to be used for erythropoiesis, which may lead to functional iron deficiency.²⁹

Curcumin may regulate hepcidin and reduce inflammation in GIT, leading to enhanced absorption of iron. HydroCurc® as superior absorption curcumin provides the female athlete with a high loading and low dosing option, that is used by other elite athletes, is tested by LGC & NSF, is made in cGMP & TGA approved facilities, has gold-standard clinical studies and has no adverse side effects.

LOW ENERGY AVAILABILITY (LEA)

The syndrome of 'Relative Energy Deficiency in Sport' RED-S refers to impaired physiological function including, but not limited to, metabolic rate, menstrual function, bone health, immunity, protein synthesis, cardiovascular health caused by relative energy deficiency. The cause of this syndrome is energy deficiency relative to the balance between dietary energy intake and energy expenditure required for health and activities of daily living, growth and sporting activities.³⁰

*Potential Performance consequences of Relative Energy Deficiency in Sport (*Aerobic and anaerobic performance):*

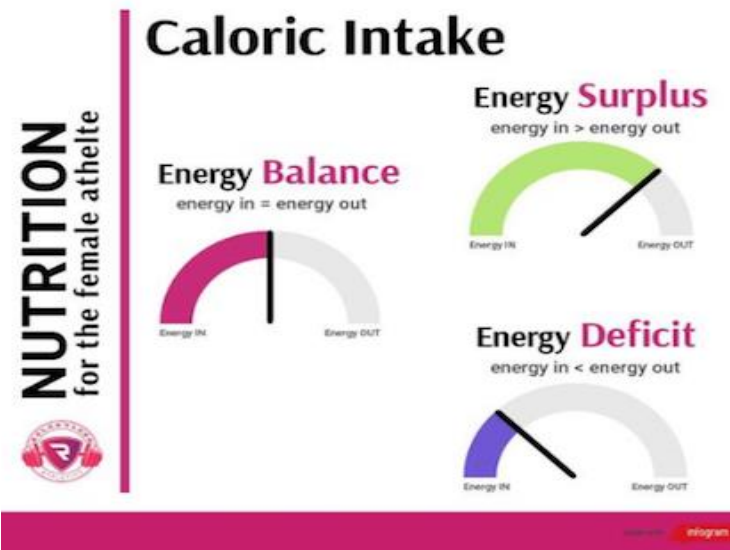


Source: <https://bjsm.bmj.com/content/bjsports/52/11/687.full.pdf>

The aetiological factor of this syndrome is low energy availability (LEA). LEA, which underpins the concept of RED-S, is a mismatch between an athlete's energy intake (diet) and the energy expended in exercise, leaving inadequate energy to support the functions required by the body to maintain optimal health and performance.³¹

HEALTH EFFECTS OF LOW ENERGY AVAILABILITY

There are several possible health effects that an athlete is exposed to when faced with LEA which include: Menstrual function; Endocrine function; Bone health; Protein synthesis; Metabolic rate; Cardio Vascular health; Psychological health; Immunity.



Source: <https://www.stack.com/a/female-athletes-not-fueling>

These can develop into severe risks for the athlete affecting performance and general well being. Carefully controlled studies on women have shown pathological effects of EA < 30 kcal/kg fat-free mass (FFM), and this state has been labeled LEA.³⁵

Bodybuilding for example, is a sport in which athletes compete to show muscular definition, symmetry, and low body fat (BF). The process of contest preparation in bodybuilding includes months of underfeeding, thus increasing the risk of LEA and its negative health consequences affecting both female and male bodybuilders. The condition is certainly not limited to professional bodybuilders, but is prevalent across all types of professional and amateur athletes, specifically females.

In women, low EA and its resulting effect on menstrual function and bone is the root of what is called the female athlete triad. The female athlete triad is a spectrum of interrelated pathophysiologic

consequences of low energy availability, menstrual dysfunction, and low bone mineral density.

ENDOCRINE FUNCTION

Once the body doesn't have enough energy, it conserves it for vital functions. This includes suppressing sex hormones required for reproduction.³² A study of 95 women found that disruption of the ovarian cycle, specifically low estrogen levels from amenorrhea, was a risk factor for coronary artery disease.³³ Female athletes who miss three or more menstrual cycles in a row are in a risky position and need to address the issue promptly. When altered hormones disrupt the menstrual cycle, the arteries that deliver oxygen and nutrients to the body and working muscles can be impaired. This can result in fatigue and impair the ability of muscles to use oxygen.³⁶ Weight loss is often a sign that the body is in an energy deficit and may indicate LEA. However, LEA is not always accompanied by weight loss. The body is amazing at conserving itself for survival and can maintain overall body weight even while EA is low. This is common among female athletes without menstrual cycles.

Women who are elite athletes or who exercise excessively on a regular basis are at risk of developing athletic amenorrhoea, which is the absence of menstrual periods. If left untreated, long-term complications of athletic amenorrhoea include increased risk of broken bones and premature ageing.

STRESS FRACTURES

Perhaps the most important organs affected by low EA are bones. Low EA directly impairs bone health and development by affecting hormones that build and restore bone, and it indirectly impairs bone by disturbing the female menstrual function and estrogen levels.

Amenorrhic athletes have been found to have a 4-5-fold risk of getting a bone stress injury, including stress fractures.³² Lower bone mineral density is commonly found in these athletes since bone protein synthesis is de-prioritized during low energy availability.³⁴ In men and women, testosterone has anabolic effects on bone, stimulating osteoclasts and increasing bone formation and calcium absorption.

PROTEIN SYNTHESIS

Research indicates that muscle protein synthesis is reduced even at LEA of 30 kcal/kg FFM/day. A negative effect on muscular protein synthesis due to LEA is implied by reduced anabolic hormones and a potential increase of cortisol in more severe or prolonged LEA, in fact, muscular adaptations important to both endurance and resistance athletes are disturbed by LEA alterations.³⁷

SOLUTION

The poor understanding by athletes and coaches of LEA and its potential health and performance consequences emphasizes the need for further research in this area. Education to increase awareness and to implement dietary, training and supplement interventions, in particular, for athletes engaged in intensive training is also vital.

The development and implementation of sports nutrition programs to increase awareness and improve knowledge of EA and within-day energy balance, as well as sports nutrition treatment strategies for athletes at risk of LEA, are warranted.³⁸ The incorporation of a standardized extract of Fenugreek [50% Fenusides] into the daily nutritional intake for an athlete may go a long way in helping.

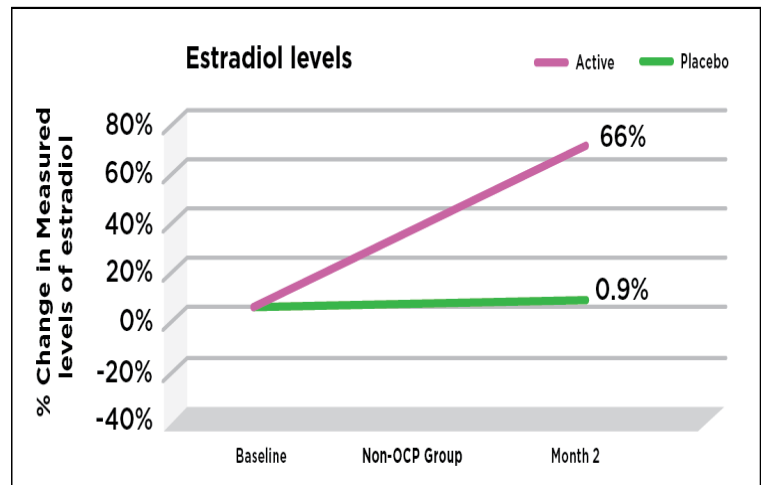
LIBIFEM®

Libifem® is the branded name for Gencor's standardized fenugreek extract. Fenugreek naturally contains over 100 phytochemical constituents, including Furostanol Saponins and Steroidal Saponins. While fenugreek has multiple applications, Libifem® has been clinically shown to help reduce normal symptoms of menopause such as hot flushes and night sweats, and promote a healthy sexual experience, sexual vitality, and desire.

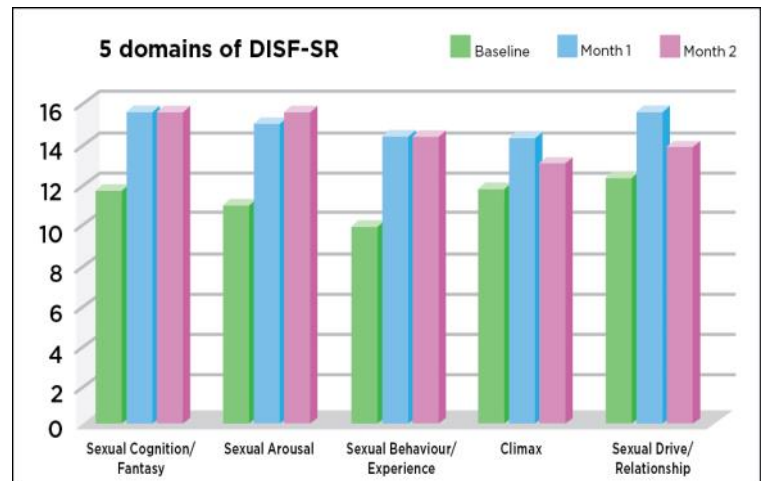
A randomized, study placebo-controlled, double-blind study covered sexual functioning and experience. Sexual function was measured using both the DISF-SR and FSFI standards. Physiological parameters related to female sexual desire were also tested. Stress, fatigue, and relationship quality were assessed using the PSS, DAS, and MFSI standards.

The study showed statistically significant results in the active group compared to the placebo group: An increase in estradiol and an increase in free

testosterone within normal female physiological limits.



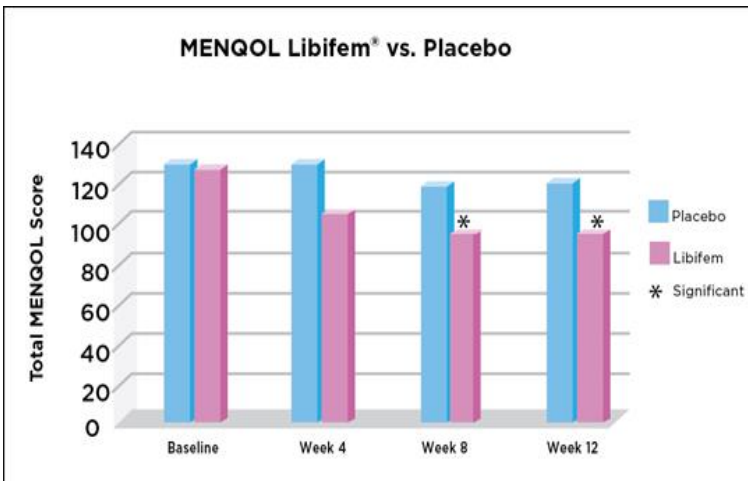
Furthermore, it had a positive significance for sexual arousal in the FSFI and a positive significance in the total score and in all 5 domains of the DISF-SR:



LibiFem® works by making the conversion of Cholesterol to DHEA - Androstenedione - Estrogen pathways more efficient and providing the body naturally with what it needs in the hormonal arena.

A second study was conducted in Australia to assess the effectiveness of Libifem® on normal symptoms of menopause in otherwise healthy women. This 12-week, double-blind, randomized, clinical trial used active and placebo arms and was conducted on women who were experiencing symptoms of menopause, such as hot flushes and night sweats, and were aged between 40 to 65 years.

Participants were given the MENQOL (Menopause Specific Quality of Life) Survey. Overall, Libifem® was shown to reduce normal symptoms of menopause (including hot flushes, night sweats and sweating) in active groups by week 12. Supplementation with active treatment group significantly reduced menopausal symptoms compared to placebo as assessed by the total MENQOL score. This was reflected in significant improvements in all sub-domains: sexual, vasomotor, psychosocial, and physical sub-domains. Secondary outcomes also showed that Libifem has no side effects.³⁹



An third study is currently underway, to assess the effectiveness of LibiFem® on muscle strength, endurance and stress markers in exercising females.

The study is an 8 week double-blind, randomized, placebo-controlled study, using 120 females (25-45 yrs). Outcome Measures of the study using LibiFem®:

- Muscle strength (1-RM Leg & Bench Press)
- Muscular Endurance (80% 1-RM LP & BP until fatigue)
- Body Composition (LMM, FM, %BF)
- Leg Power (FTP)
- Pathology (cortisol, T, CRP)

To summarize, Fenugreek, increased estradiol within normal healthy range and it increase free testosterone within normal female physiological limits. The ingestion of Fenugreek increases MPS above resting EB in a dose-dependent manner. Ingestion of Libifem® may enhance rate of skeletal muscle protein synthesis during short-term ED and could in the long term preserve muscle mass.

RELEVANCE TO FEMALE ATHLETES

Supplement and Sports Nutrition Manufacturers have the potential to minimize negative effects of LEA in women (endocrine function, bone health, protein synthesis, muscular strength & endurance) by adding clinically studied, safe and effective supplements to their formulas. The ingestion of Libifem® may enhance rate of skeletal muscle protein synthesis during short-term ED and could in the long term preserve muscle mass.

THE IMPORTANCE OF FEMALE ORIENTATED RESEARCH

Formulations marketed towards males focus on testosterone (anabolic hormone) enhancers in light of testosterone's known androgen-regulating physiological functions. Specifically, alterations in body composition, increased energy and muscle strength, changes in well-being and mood.⁴⁰ Whereas formulations marketed towards females focus on beauty supplements (e.g. anti-ageing), weight loss, health value and illness prevention, companies are still just producing pink bottles of sparkly fat-burner mojitos.⁴¹

However, in the past very recent years there has been an increased use of supplements targeted at women for physical performance, for brands to resonate with female consumers is to engage them with messages of strength, energy, empowerment and athleticism, not just weight-loss and skinny promises.⁴² The relative scarcity of female-led clinical research on either safety or efficacy, and trying to extrapolate male-dominated research to apply to the female athlete or fitness enthusiast is of concern.⁴³

Companies that recognize that they need to include ingredients that meet the prerequisites of a new informed market of women athletes, will succeed in a cluttered marketplace. Checking the boxes will be imperative to succeed: clinically tested, specifically tested on women, excellent safety & efficacy profiles, easy to use and finally, address more than weight loss and improve performance, endurance, recovery and real athletic concerns.

Athletes, want products they can trust and that also offer real, scientifically proven benefits. There is a need for both greater transparency and claims backed by robust scientific evidence. However, in the U.S., only 15% of people believe that nutrition and performance drinks actually deliver on their claims.⁴⁴

Research continues for advancement in the women sports nutrition with key performers being fat burners and proteins. But, the new research in case of ingredients sheds light on components like iron, antioxidants, plant protein, vitamin D, creatine, curcumin, calcium, and PEA.

OVERCOMING MENSTRUAL PAIN

Given the improving but still persistent trend of scant sports nutrition research on women, often due to fears over how menstruation and hormone changes could affect results, it is challenging to provide women the ingredients they need to be stronger and perform better. A 2017 study⁴⁴ published in the European Journal of Sport Science found that among the more than 6 million participants tracked in the 1,382 sports and exercise medicine research papers that the researchers analyzed, only 39% were female. Claims based on clinical research performed on men may not be applicable to women.

Women's bodies are biologically and physiologically different from males, the former carry 6%-11% more body fat than the latter, due to estrogen, as it suppresses fat oxidation, making it more difficult for women to lose fat. Women also metabolize some nutrients differently than do men, resulting in higher requirements for iron, calcium, vitamin D, and folate, to name a few. Women also have lower sweating rates than men, mostly due to a lower metabolic rate and smaller body mass. And women have to deal with the rise and fall of estrogen and progesterone, which affects energy and water retention, as well as physical performance.

Menstruation pain can affect performance in these athletes' training regimes and competitions. As some studies have shown the menstrual cycle could be related to performance, nutrient utilization, recovery.⁴⁵ This is extremely important for the adolescent female athlete to understand as research demonstrates a relationship between the ABSENCE of ovulation and an increased occurrence of injuries and decreased performance levels.⁴⁶⁻⁴⁸ Regular menstruation is a necessary indicator that the hormones are cycling to help the body maintain homeostasis and function optimally.

For instance, while rising estrogen in the pre-ovulatory phase helps your ovaries mature an egg, estrogen also acts to tell other cells to increase

their sensitivity to insulin allowing for increased blood glucose uptake.⁴⁹ For the female athlete, this means improved performances at higher intensities. At other cells, estrogen acts as an anti-inflammatory agent leading to reduced fatigue and improved recovery times after training.⁵⁰ Meanwhile, estrogen has also been shown to increase joint laxity and has been postulated to increase a female athlete's risk of knee injury^{48,51} It is important to understand that hormones do NOT act alone. Studies have shown the increased laxity of the ACL associated with increased estrogen are blunted with the presence of testosterone. This is extremely important as testosterone is a hormone that also fluctuates throughout the menstrual cycle.⁴⁶ As one hormone increases and messages its receptor cells, other hormones may then be reduced in concentration or increased in production in response. This relationship and cyclical nature of the hormones of a female are vital to help the body perform at its highest.

As menstrual health could be an indicator for energy availability, low energy environments lead to fatigue. Fatigue has been repeatedly shown to influence injury rates.^{50,52} In a study on high school female athletes in 2012⁴⁷, researchers cited females who experienced menstrual irregularities (9 or fewer cycles) were almost 3x as likely to sustain a musculoskeletal injury compared to athletes reporting normal cycles. So vitally necessary, to the female athlete, the solution is not stop the cycles but cope with them better, especially with regard to pain tolerance.

Menstrual pain is the leading gynecological condition reported by women and is the prime cause of pelvic pain (WHO). 45 - 95% of all females experience 8 - 72 hours of menstrual pain.

DEALING WITH MENSTRUAL PAIN

Menstrual cramps, also referred to as dysmenorrhea are throbbing pains experienced in the lower abdomen. Besides the chilling pains in the lower abdomen, some women also experience nausea, loose stools, headache, and dizziness. The bottom line is that hormonal shifts that drive the menstrual cycle can affect multiple parts of the body, including muscle, bone, endurance, energy level and attention.

Birth control can stop period pain if cramps are caused by a hormone imbalance. Balancing the levels of estrogen and progesterone helps thin the uterine lining so it sheds more easily. Hormonal birth control also regulates the length and frequency of your period. While hormone stabilization and predictable cycle length are common benefits of oral contraceptives, manipulating the menstrual cycles to avoid performance changes may have dangerous consequences as mentioned earlier.

The hormone prostaglandin can cause muscle contractions and pain. Anti-inflammatory medicines like ibuprofen can provide fast-acting relief by reducing the amount of prostaglandins in the body, but there are severe risks associated with long term painkiller use.

Many athletes use the painkillers/non-steroidal anti-inflammatory (NSAID) like Advil/ibuprofen or Aleve/naproxen on an almost daily basis. In a US survey it was found that up to 70% of distance runners and other endurance athletes report that they down the pills before every workout or competition,⁵³ viewing the drug as a pre-emptive strike against muscle soreness and for many female athletes a much needed relief to menstrual pains. In British survey, 60% of amateur athletes took over-the-counter anti-inflammatories like ibuprofen and naproxen to support their performance or recovery at least once a week.⁵⁴

But a valuable new study joins growing evidence that ibuprofen and similar anti-inflammatory painkillers taken before a workout do not offer any benefit and may be causing disagreeable physical damage instead, particularly to the intestines.⁵³

Studies have already shown that strenuous exercise alone commonly results in a small amount of intestinal trauma. A study found that cyclists who rode hard for an hour immediately developed elevated blood levels of a marker that indicates slight gastrointestinal leakage.⁵⁵ But the most common side-effect of NSAID's is gastrointestinal damage, and ibuprofen consumption by athletes is not harmless and should be strongly discouraged.

Alternatively athletes (and brands) are claiming that CBD is the new cure all that can address everything from headaches to sore joints to inflammation to sleep issues. "It's a wonder drug with zero side effects and bro, it's not even really a drug." But it is

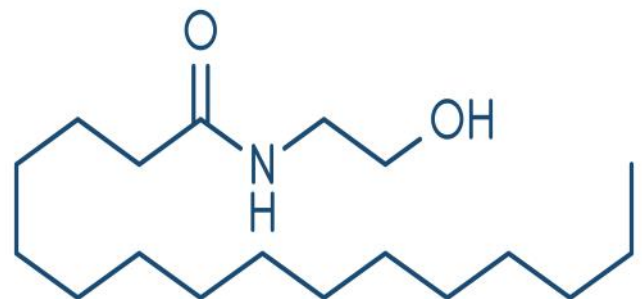
a drug and it can present serious problems for the professional athlete, besides from doping issues, there is the matter of a the lack of clinical and scientific research on humans. Some people experience side effects from CBD. According to 2017 research,⁵⁶ the most common side effects of CBD use are:

- fatigue
- diarrhea
- changes in weight
- changes in appetite

There are still a lot of unknowns about CBD and its impact on athletes, but athletes may find it useful for pain and inflammation, so what is out there that works on the same pathways as CBD but is legal and safe?

SOLUTION

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, to injury and stress.



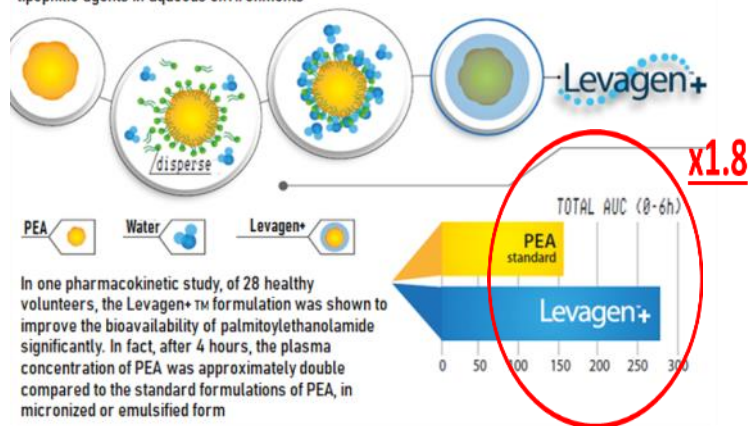
palmitoylethanolamide

Levagen®+ is a cold water dispersible palmitoylethanolamide (PEA) powder, specifically designed to increase bioavailability. The product is powered by the LipiSpense® 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. **A pharmacokinetic study** was conducted to prove Levagen+®'s superiority in absorption over standard PEA. The study examined the impact of LipiSpurse on bioavailability of Levagen® and found that the Levagen+® group having a significantly increased plasma PEA concentration.⁵⁶

LipiSpurse® Technology

A new system created to improve the dispersion of lipophilic agents in aqueous environments



Levagen+® is fast-acting, endogenous, safe, and scientifically backed and Levagen+® acts upon multiple pathways to exert its analgesic and anti-inflammatory actions, thus providing numerous benefits compared to other anti-inflammatories, such as joint health, exercise recovery, sleep quality and pain.

It also has a special advantage, only requiring 10% excipient load, so delivering a high active ingredient payload. The ability for it to be incorporated into a wide range of formats also allows Levagen®+ to be a strong addition to any sports nutrition or supplement (particularly with its low dosage requirement ~150mg - 300mg).

Levagen®+ has numerous clinical studies proving safety and efficacy. It is also accepted as a legal supplement worldwide.

Gencor has completed peer-reviewed studies and a pharmacokinetic study (referenced above).

Levagen® Osteoarthritis Study: examined 111 patients with osteoarthritis symptoms to find a dose-dependent improvement in WOMAC (reduce joint pain, stiffness and improved function). A reduction in anxiety sub-domain, improvement in quality of life and a reduction of paracetamol use was also observed.⁵⁷

Levagen+® Exercise Recovery Study: evaluated exercise recovery using 28 healthy male athletes which were dosed with Levagen+ for 4 days to measure muscle recovery after acute exercise. Levagen+ group had lower blood concentration of myoglobin than placebo, signifying reduced muscle damage.⁵⁸

Other studies which are currently at various stages in the publication process, include:

Acute Short-Term Joint Pain Study: 2-week randomized, double-blind, placebo-controlled study to assess the effectiveness of PEA for reducing joint pain which has been accepted for publication.

PEA versus Ibuprofen Study: Double-blind, randomized controlled study to evaluate the effect of orally dosed Levagen+ compared to Ibuprofen for reducing pain severity and duration of headaches in healthy male and female participants aged 18 years+. This study is currently under peer review and expected to be published within 1st quarter 2021.

Sleep Study: A double-blind, randomized, placebo-controlled study to measure the effects of Levagen+ on sleep showed that Levagen+® significantly decreased the time taken to get to sleep at night and the time taken to feel fully awake in the morning. Participants had improved cognitive function at waking. This study is complete and awaiting submission to a journal in 1st quarter 2021.

There are also an additional nine human clinical studies that are currently underway.

In summary, Levagen®+ serves as an effective alternative to NSAID's and CBD for female athletes for the following reasons:

- Gold-standard clinical studies
- Approved by elite athletes
- Is a Certified Informed-Ingredient (LGC)
- Made in cGMP & TGA approved facilities
- Has no adverse effects



INGREDIENT

WHAT CHANGES CAN BE MADE IN THE NUTRACEUTICAL MARKET TO TAP INTO THE POTENTIAL OF FEMALE SPORTS NUTRITION?

Even though there are physiological and biological differences between male and female athletes, some nutritional supplements are dually beneficial. According to the International Olympic Committee (IOC) consensus, one of the reasons athletes, female or male, often consume supplements is to gain a performance improvement indirectly from better recovery, optimizing composition, reducing risks of injury and illness, or to tolerate pain and soreness.⁵⁹

An athlete's nutritional requirement is often determined by their training regime, that's nothing but an integration of intensity, frequency, and duration of the workout. This stands true for both genders and female athletes want to see products that specifically cater to their needs. The needs indicate fulfilling post-workout demands, endurance, relaxation and recovery after a long hard day of performance and workout. They want products that enhance their workouts holistically by reducing stress, increasing restful sleep, and provide lean muscle building rather than bulk.

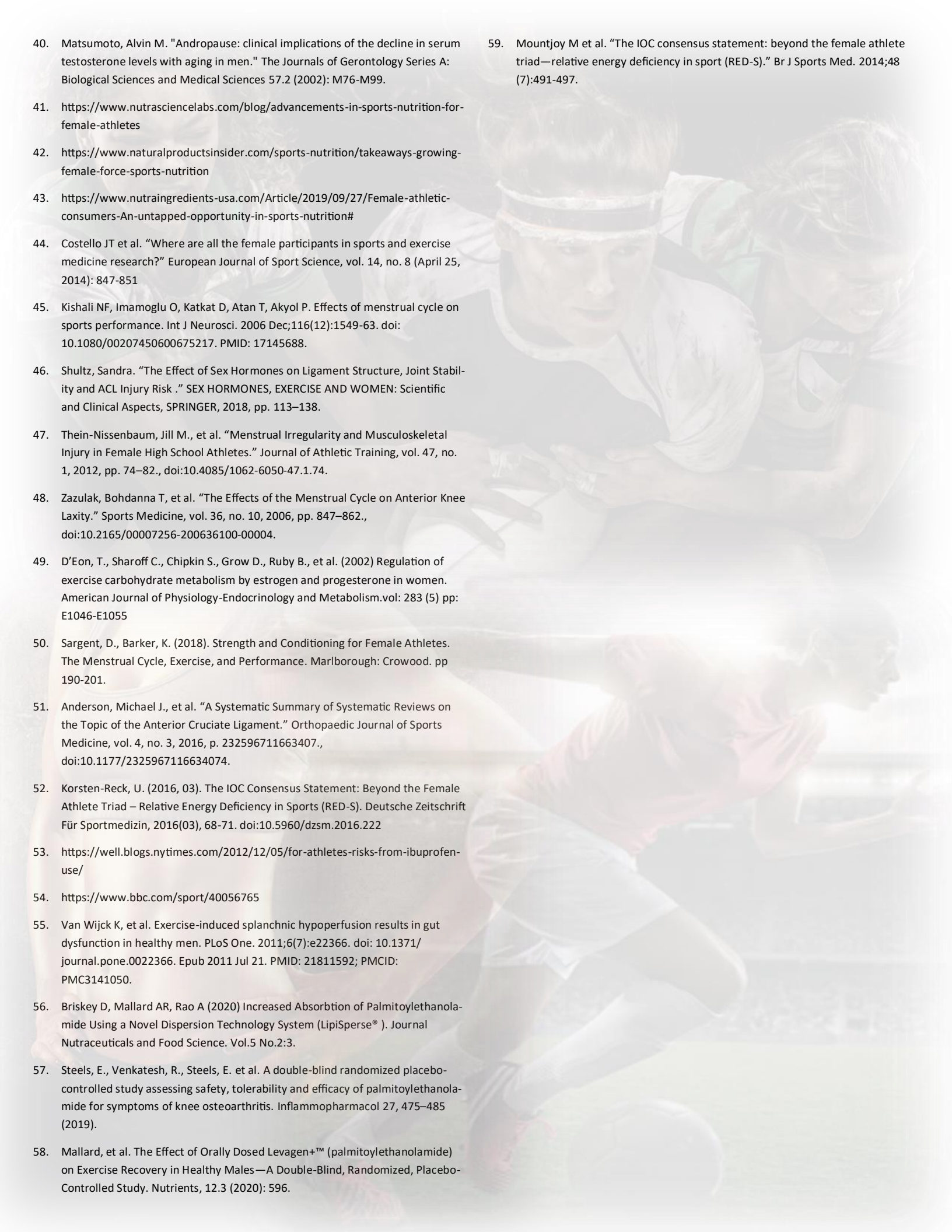
Innovative ingredients that can help keep muscle cramps at bay, provide ample bone health and oxygen support for muscles along with the differentiating demands for vegan and clean diets - these are a few areas that can swing/influence purchase decisions in the women sport's nutrition market positively. But a product needs more than progressive bona fides to succeed with active women. It also needs to produce a palpable effect. So products that can enhance their active nutrition performance while making them feel great will be key drivers for this category.

This presents an excellent opportunity for manufacturers that utilize research-backed branded ingredients to build trust in their products with consumers. If the evidence is there, consumers will respond to it positively.⁴⁴



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