# Maca SAP

### Science-based formulation for mood support and sexual health

Maca has long been heralded as a superfood, due to its rich nutritional composition consisting of dietary fiber, amino acids, polyphenols, glucosinolates and other vitamins and minerals.\* It has been used since ancient times for a host of beneficial effects, and in recent times these benefits have been confirmed clinically.\* Maca has proven to be useful in the improvement of male sexual health, both physiological and mental.\* Maca supplementation has been shown to reduce symptoms of male sexual dysfunction and increase sexual desire without affecting hormone levels.\* Maca is also reported to help improve erectile dysfunction and improve physical performance.\* Interestingly, maca does not affect hormone levels in adults of reproductive age, however it has a positive impact in regulation of estrogen, follicle-stimulating hormone, luteinizing hormone and sex hormone-binding globulin in menopausal and post-menopausal women.\* Furthermore, maca alleviated symptoms of anxiety and depression in older women.\* The mental health benefits of maca have made it an excellent adjunctive option to treat side effects of anti-depressant drugs such as serotonin reuptake inhibitors (SSRIs), where maca can help to ameliorate sexual dysfunction occurring from SSRI intake.\*

**Maca SAP** provides a unique blend of 3 different organic maca phenotypes that can help promote healthy mood balance, support emotional and physical aspects of sexual health and provide antioxidants.\*

## **ACTIVE INGREDIENTS**

Serving Size: 2 Capsules	Amount per Serving	Servings: 60 % Daily Value	
Organic Maca (Lepidium meyenii) providing 0.4% macamides and macaenes	1.5 g	**	

\*\* Daily Value not established.

**Other ingredients:** Vegetable magnesium stearate and silicon dioxide in a capsule composed of vegetable carbohydrate gum and purified water.

**Contains no:** Gluten, soy, wheat, eggs, dairy, yeast, citrus, preservatives, artificial colors and flavors, starch or sugar.

#### This product is non-GMO and vegan friendly.

Maca SAP contains 120 capsules per bottle.

## **DIRECTIONS FOR USE**

Adults: Take 2 capsules twice daily or as directed by your healthcare practitioner.

**Duration of use:** Consult a healthcare practitioner for use beyond 3 months. **Menopausal and Post-menopausal women only:** Consult a healthcare practitioner for use beyond 6 weeks.

## INDICATIONS

#### Maca SAP:

- Helps improve sexual health in men and women.\*
- May help promote mood balance, especially in menopausal and post-menopausal women.\*
- May help in the management of symptoms of menopause.\*

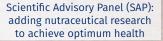
## **CAUTIONS & WARNINGS**

Consult a healthcare practitioner prior to use if you are pregnant or breastfeeding; if you have high blood pressure; if you are taking antidepressants; if you are taking blood thinners; or if you suffer from any psychological disorder and/or condition such as frequent anxiety or depression.

## **PURITY, CLEANLINESS & STABILITY**

All ingredients listed for each **Maca SAP** lot number have been tested by an ISO 17025 accredited third-party laboratory for identity, potency, and purity.

\* 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.



NFH

Maca SAP

Menopause Support\*

DIETARY SUPPLEMENT

120 CAPSULES



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For healthcare professional use only.

Maca (Lepidium meyenii), also known as Peruvian ginseng, is a plant belonging to the family Brassicaceae, and is native to the Peruvian Andes, where it has been cultivated for the past 2000 years. [1] The main parts of maca used for therapeutic purposes are the hypocotyls and main taproot, which are rich in dietary fibre, protein and starch. They also contain bioactive compounds such as polyphenols, macamides, macaenes, glucosinolates and macahydantoins, making maca nutritionally denser. [2] The root contains about 37-77% starch comparable to sweet potato, and about 10% non-starch polysaccharides. Dietary fiber from maca has better swelling capacity and inhibition of glucose absorption. Maca is also rich in amino acids, endogenous enzymes, and minerals such as calcium, magnesium, sodium, potassium, copper, zinc, cobalt and iron. [2] Macamides, which are secondary amides present in the maca root, are known to have neuroprotective effects, while macaenes are suggested to contribute to neuroprotection and sexual function. [1,2] Interestingly, clinical evidence shows maca can be beneficial in male and female reproductive health. The mechanism of action via which this benefit is achieved is not through changes in hormone levels. This eliminates the detrimental effects of phytoestrogens or excess testosterone increase. In fact, a clinical study administering maca to healthy men concluded that maca does not affect testosterone, estrogen or follicle-stimulating hormone, with no adverse event reported, making maca a safe supplement to improve sexual function. [3]

#### **CLINICAL EVIDENCE FOR MALE SEXUAL DYSFUNCTION**

There is significant clinical evidence that has established a strong connection between maca and improvement of male sexual function. Maca has shown to improve not only physiological but also emotional aspects of male reproductive health. A pilot study conducted with 9 men showed that supplementation with 1500 mg or 3000 mg/day of maca for 4 months showed an improvement in sperm count, sperm motility and seminal volume without changing follicle-stimulating hormone, prolactin, testosterone, and estradiol levels. [4] Another pilot study showed administration of 2000 mg/day of maca for 2 weeks significantly improved sexual desire and cycling performance in 8 male cyclists. [5] In a 12-week randomized, double-blind, parallel trial, men aged 21-56 years were given 1500 mg, 3000 mg of gelatinized maca or placebo daily, with clinical measurements at 4, 8 and 12 weeks. At 8-12 weeks of treatment, maca showed an independent effect on sexual desire without changing levels of testosterone. [6] A further physiological response was observed on erectile dysfunction in a randomized double-blind clinical trial of 50 study participants. Supplementation with 2400 mg maca for 12 weeks showed an improvement in erectile dysfunction parameters with improved social and physical performance compared to the placebo group. [7]

#### THERAPEUTIC POTENTIAL FOR FEMALE SEXUAL HEALTH

Interestingly, while maca does not appear to affect hormone levels of men and women in the reproductive age group, it appears to have beneficial hormone balancing benefits in menopausal women. Maca (200 mg/day) or placebo was administered to menopausal women over a period of 3 months (n=102) and 4 months (n=66) in a randomized, double-blind, placebocontrolled multi-center trial. Maca administration appeared to stimulate production of estrogen, lower blood follicle-stimulating hormone, and increase HDL cholesterol. The control group also experienced lower and less severe incidents of hot flashes, night sweating and other menopause symptoms. [8] In another study, administration of 3500 mg of maca daily for 6 weeks significantly improved symptoms of anxiety, depression and sexual dysfunction without affecting levels of follicle-stimulating hormone, luteinizing hormone or sex hormone-binding globulin in 14 menopausal women participating in a randomized, double-blind, placebo-controlled, crossover trial. [9] In addition to sexual and hormonal health, maca supplementation also showed psychological benefits, where administration of 3300 mg/day of maca to 29 post-menopausal women for 6 weeks significantly reduced diastolic blood pressure and depression. [10] Further clinical trials are required to help understand this therapeutic effect and bolster confidence in maca as a non-hormonal support for management of symptoms of menopause.

Maca has even proven effective in improving sexual dysfunction brought on by antidepressants such as serotonin reuptake inhibitors (SSRIs). In a double-blind, parallel, randomized pilot study, maca was administered (1500 mg and 3000 mg) to 17 women and 3 men suffering from SSRI-induced

## **RESEARCH MONOGRAPH**

sexual dysfunction. All participants showed an improvement in libido and reduction in indicators of sexual dysfunction, with data suggesting a dose-dependent effect, with improved results at the 3000 mg dose. [11] These findings were corroborated further with a double-blind placebocontrolled trial where 45 women with SSRI-induced sexual dysfunction were supplemented with 3000 mg/day of maca root powder for 12 weeks. Women supplemented with maca showed lower sexual dysfunction scores compared to the placebo group. [12]

#### **MENTAL HEALTH AND OTHER BENEFITS**

An observation of the clinical studies above reveals that maca ameliorates sexual health by improving not only physiological but also psychological aspects of sexual dysfunction. Several studies point to the evidence of improved mental state, where measurement parameters included a self-assessed and reported improvement of sexual desire in men [5,6]. Similarly, maca supplementation appears to decrease symptoms of anxiety and depression in menopausal and post-menopausal women. [9,10] Another study looking into the effects of maca supplementation at different altitudes observed improvement in mood of the participants. A black or red maca dose of 3000 mg or placebo per day was given to 175 adults for 12 weeks in a randomized, double-blind trial. Maca consumption (*red and black*) showed an improvement in energy and mood of the participants with an increase in health-related quality of life scores (HRQL) and chronic mountain sickness (CMS) score. [13] Further clinical studies should help shed light on the mental health benefits of maca.

#### FERTILITY

Preclinical and early clinical evidence suggest maca's potential for improving fertility in men and women. [5, 9, 14, 15] In a double-blind, randomized, placebo-controlled pilot trial in 20 healthy men (aged 20-40 years), the effects of maca (1.75 g) on semen parameters and serum hormone levels were studied for 12 weeks. Sperm concentration and motility showed rising trends compared to placebo even though levels of hormones did not change significantly after 12 weeks. These results indicate that maca possesses fertility-enhancing properties in men. [16] However, more clinical studies are warranted to confirm the findings and the optimal dosage for improving fertility.

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## INDICATION SPECIFIC DOSAGE SUMMARY BASED ON HUMAN CLINICAL RESEARCH#

#Please note these suggestions are guidelines based on the clinical studies. Evidence for efficacy and safety have been qualitatively (study quality in terms of study design, sample size, appropriate methods of analysis, use of appropriate placebo/control, bias etc) assessed and have been rated using a 5 star **\*** rating classification.

\* 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.

Indication	Suggested dosage	Supporting evidence	Study design	Outcome measures/ selection criteria for studies	Safety	Evidence quality rating		
Female Sexual Health								
Hormonal balance <sup>1</sup>	3 capsules/ day	Stimulation of E2 production, suppressed FSH, increased HDL, reduced menopausal symptoms*	Randomized, double- blind, placebo controlled (n=124, 3 months and 4 months); 2000 mg/day	FSH, E2, progesterone, LH, cholesterol, TG, LDL, HDL. Menopausal symptoms - Green's Score (GMS), Kupperman's Index (KMI). Multivariate analysis	No adverse events	****		
Depression and blood pressure in postmenopausal women <sup>2</sup>	5 capsules/ day	Reduction in depression, improvement in diastolic blood pressure*	Randomized, double- blind, placebo- controlled trial (n=29, 12 weeks); 3300 mg/day	Estradiol, FSH, SHBG, TSH, lipid profile, glucose, serum cytokines. Greene Climacteric Scale (GCS) and SF-36 Version 2, height, body weight, blood pressure. One-way repeated-measures ANOVA	No adverse events	****		
SSRI-induced sexual dysfunction <sup>3</sup>	4 capsules/ day	Improvement in sexual experience and sexual function scores with 3g dose*	Randomized, double- blind, placebo- controlled parallel trial (n=16, 12 weeks); 1500 mg/day or 3000 mg/day	Arizona Sexual Experience Scale (ASEX), Massachusetts General Hospital Sexual Function Questionnaire (MGH-SFQ), Hamilton Rating Scale for Depression and Anxiety, Clinical Global Impression of Severity, and Improvement Scales. Wilcoxon Paired Signed Ranks test, regression analysis	No adverse events	****		
SSRI-induced sexual dysfunction (women) <sup>4</sup>	4 capsules/ day	Higher remission rates, improved sexual experience and sexual function scores*	Randomized, double- blind, placebo- controlled trial (n=45, 12 weeks); 3000 mg/day	Arizona Sexual Experience Scale (ASEX), Massachusetts General Hospital Sexual Function Questionnaire (MGH-SFQ). Paired t-test, independent samples t-test, relative risk and odds ratio	No adverse events (flu symptoms in 3 subjects, difficult to associate symptoms with maca)	****		
Psychological symptoms and sexual dysfunction <sup>5</sup>	5 capsules/ day	Reduced anxiety and depression scores and psychological symptom and sexual dysfunction scores*	Randomized, double- blind, placebo controlled (n=14, 6 weeks); 3500 mg/day	Estradiol, FSH, LH, SHBG. Greene Climacteric Scale for menopausal symptom assessment. Kolmogorov- Smirnov test, one-way repeated-measures ANOVA	No adverse events	***		



Indication	Suggested dosage	Supporting evidence	Study design	Outcome measures/ selection criteria for studies	Safety	Evidence quality rating		
Male Sexual Health								
Sexual desire <sup>6</sup>	3-4 capsules/ day	Increase in sexual desire*	Randomized, double- blind, placebo controlled (n=57, 12 weeks); 1500 mg/day or 3000 mg/day	Self-reported sexual desire, Hamilton Depression Rating Scale, radioimmunoassay for T and oestradiol	No adverse events	****		
Sexual well- being and erectile function <sup>7</sup>	3-4 capsules/ day	Improvement in erectile function scores, psychological performance scores, social and physical performance scores*	Double-blind, randomized, placebo- controlled (n=50, 12 weeks); 2400 mg/day	International Index of Erectile Function (IIEF-5), Satisfaction Profile (SAT-P)	No adverse events	****		
Sexual desire <sup>8</sup>	3 capsules/ day	Improvement in cycling time performance and sexual desire*	Randomized, double- blind, placebo controlled (n=8, 14 days); 2000 mg/ day	Endurance - checked with 40 km cycling trial- time, heart rate, rate of perceived exertion. Sexual desire inventory (SDI)	No adverse events	***		
Sperm parameters <sup>9</sup>	2 capsules/ day	Increase in semen volume, sperm count, motility, no hormonal changes*	Study (n=9, 4 months); 1500 mg/day	Semen analysis as per WHO manual, hormone assay for LH, FSH, PRL with immunoradiometric assay (IRMA). T and E2 measured with radioimmunoassay. Student t-test	No adverse events	*		

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