

Raw Maca 750 mg

TECHNICAL SUMMARY

Maca (*Lepidium meyenii*) is native to the Andes region of Peru, where it has a long history of use, both as a food and a general energy tonic.* Modern scientific studies indicate that natural constituents in maca may help to support healthy sexual activity in males, without exerting any direct effect on endocrine function.* Protocol for Life Balance® Raw Maca is gelatinized to remove starch for a more concentrated product.

Manufacturing and Composition: The concentrated maca used in this product is made of the cold-dried roots of a blend of 80% black, 15% red-purple and 5% yellow maca. A unique cold gelatinization process is used to remove starch from the root, leaving a more concentrated powder that is easier to absorb and digest.

The maca powder used in this product is not standardized for any bioactive compounds; however maca roots are known to possess naturally occurring macaridine, macaene, macamides, maca alkaloids, phytosterols and glucosinolates.

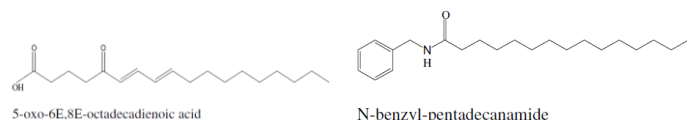


Figure 1: Macaene (left) and one form of macamide (right). Macaene and macamides are specific to maca.

Allergen and Additive Disclosure: Not manufactured with yeast, wheat, gluten, soy, corn, milk, egg, fish, shellfish or tree nut ingredients. Produced in a GMP facility that processes other ingredients containing these allergens.

Delivery Form: Vegetable capsules.

ROLE AS NUTRIENT/FUNCTION

Maca (*Lepidium meyenii* Walpers) is a plant that grows exclusively in the harsh climate of central Andes between 4,000 and 4,500 m altitude. It is part of the Brassicaceae family and has been cultivated for more than 2,000 years. The root is traditionally used as a food and a tonic by native Peruvian population.

The exact nature of the biologically active compounds responsible for maca's effects in humans is not known. However, maca constituents including macamides and macaenes have shown promising effects on animal models.

Maca has been extensively studied in humans. While its clinical effects are well demonstrated (see clinical validation section), it has been repeatedly shown that it does not interfere with endocrine pathways.

NATUROKINETICS®

Liberation: Maca vegetable capsules dissolve in water within 60 minutes using a USP method of disintegration.

Absorption: In a pharmacokinetic study in animal models, after oral administration of a macamide (N-3-methoxybenzyl-palmitamide) derived from maca, the

Supplement Facts

Serving Size 1 Veg Capsule

Amount Per Serving

Organic Raw Maca Root (6:1 Concentrate) (<i>Lepidium meyenii</i>) (Gelatinized - vegetarian)** (Equivalent to 4,500 mg of fresh Maca Root)	750 mg*
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* Daily Value not established.

Other ingredients: Hypromellose (cellulose capsule), Hydroxypropyl Cellulose, Silicon Dioxide and Magnesium Stearate (vegetable source).

- **Healthy Sexual Function***
- **Peruvian Maca**

SUGGESTED USAGE: Take 1 capsule 1 to 2 times daily, or as directed by your healthcare practitioner.

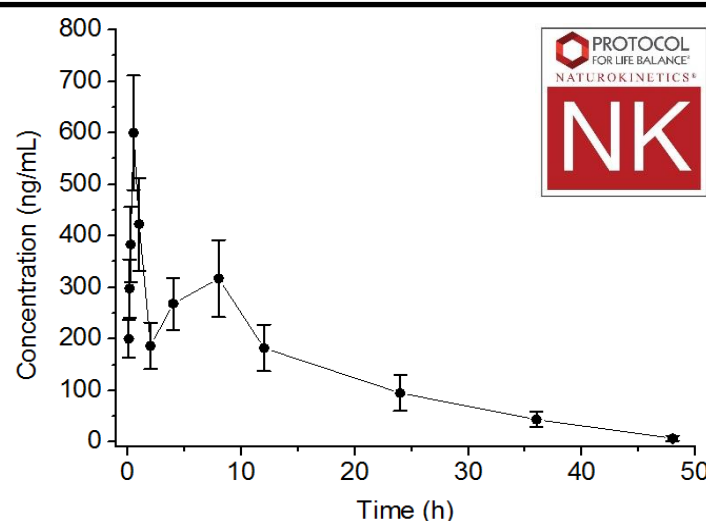


Figure 2: Mean plasma concentration-time plots after a single oral dose of 80 mg/kg of N-3-methoxybenzyl-palmitamide in rats. n=6.

maximum concentration of the compound in the blood occurred 30 minutes after ingestion.

The significance of these pharmacokinetics data in animals has not been confirmed in humans. There is no published data regarding the exact site of absorption of maca's bioactive compounds within the digestive tract nor regarding the rate of absorption of these compounds.

Distribution: In the same pharmacokinetic study in animal models, macamide was mainly distributed in the stomach, lung, and spleen tissues with small amounts also found in the heart, kidney, liver and reproductive organs. Distribution information regarding maca's bioactive compounds in humans is unavailable.

Metabolism: Maca's bioactive compounds metabolism in the body is unknown.

Elimination: In the same pharmacokinetic study in animal models, the elimination half-life of macamide was 7.44 hours.

CLINICAL VALIDATION

- In a 12-week randomized, double-blind, placebo-controlled, clinical study, 57 healthy volunteers (21-56 y.o.) received up to 3,000 mg/d gelatinized maca in three divided doses. The authors observed a significant increase in sexual desire in the maca group vs. baseline and vs. placebo.

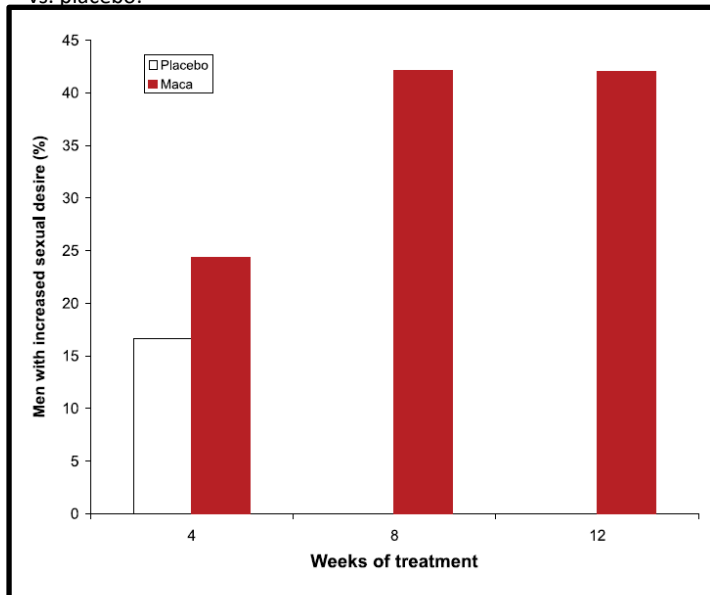


Figure 3: Prevalence of men with increased sexual desire in the placebo and maca groups. 4 weeks of treatment p=NS vs. placebo. 8 weeks: p<0.008 between groups. 12 weeks: p<0.006 between groups. There were no men with increased sexual desire at week 8 and 12 in the placebo group.

- In a 4-month open-label clinical study, 9 healthy men (24-44 y.o.) received up to 3,000 mg/d gelatinized maca. The authors observed significant changes in semen variables, including volume sample, total sperm count, motile sperm count, sperm mobility (grades a+b) (p<0.05).

SAFETY INFORMATION

Tolerability: Maca is remarkably safe as it is traditionally consumed as a food up to 70 g/d. In clinical studies, it is typically well tolerated.

Contraindications: None known.

INTERACTIONS

Drug Interactions: None Known.

Supplement Interactions: None Known.

Interaction with Lab Tests: None Known. It is important to note that there is no known interaction with endocrine functions as tested in *in vitro*, *in vivo*, and in clinical studies.

STORAGE

Store in cool, dry, and dark environment in sealed container. Store in ambient conditions (< 80°F). Protect from excessive heat, moisture, air and light.