



NATURAL HEALTH PRODUCT

MACA – *LEPIDIUM MEYENII*

This monograph is intended to serve as a guide to industry for the preparation of Product Licence Applications (PLAs) and labels for natural health product market authorization. It is not intended to be a comprehensive review of the medicinal ingredient.

Notes

- ▶ Text in parentheses is additional optional information which can be included on the PLA and product label at the applicant's discretion.
- ▶ The solidus (/) indicates that the terms and/or the statements are synonymous. Either term or statement may be selected by the applicant.

Date

March 6, 2013

Proper name(s)

Lepidium meyenii Walp. (1843) (Brassicaceae) (USDA 2011; McGuffin et al. 2000)

Common name(s)

- ▶ Maca (USDA 2011; McGuffin et al. 2000)
- ▶ Peruvian ginseng (USDA 2011; NS 2012)

Source material(s)

- ▶ hypocotyl (Meissner et al. 2006)
- ▶ root (Dording et al. 2008)

Route(s) of administration

oral

Dosage form(s)

- ▶ The acceptable pharmaceutical dosage forms include, but are not limited to capsules, chewables (e.g. gummies, tablets), liquids, powders, strips or tablets.



- ▶ This monograph is not intended to include foods or food-like dosage forms such as bars, chewing gums or beverages.

Use(s) or Purpose(s)

Statement(s) to the effect of

- ▶ Helps to support emotional aspects of sexual health (Shin et al. 2010; Zenico et al. 2009; Brooks et al. 2008; Dording et al. 2008; Meissner et al. 2006, 2005; Gonzales et al. 2002).
- ▶ Helps to support healthy mood balance during menopause (Brooks et al. 2008; Meissner et al. 2006).
- ▶ Provides antioxidants (Brooks et al. 2008; Vecera et al. 2007).

Dose(s)

Statement(s) to the effect of

Sub-population(s)

adults (≥ 19 yr)

Quantity(ies)

Antioxidant:

Up to 3 g dried root/hypocotyl or equivalent, per day (Brooks et al. 2008; Vecera et al. 2007)

Mood balance during menopause:

2 - 3.5 g dried root/hypocotyl or equivalent, per day (Brooks et al. 2008; Meissner et al. 2006)

Sexual health:

3 - 3.5 g dried root/hypocotyl or equivalent, per day (Shin et al. 2010; Zenico et al. 2009; Brooks et al. 2008; Dording et al. 2008; Meissner et al. 2006; Meissner et al. 2005; Gonzales et al. 2002)

Directions for use

No statement required.

Duration of use

Statement(s) to the effect of

Menopausal and Post-Menopausal Women only:

Products providing ≥ 3 g dried root/hypocotyl, per day:

For use beyond 6 weeks, consult a health care practitioner (Brooks et al. 2008).

Products providing 0.6-3 g dried root/hypocotyl, per day:



For use beyond 3 months, consult a health care practitioner (Zenico et al. 2009; Dording et al. 2008; Meissner et al. 2006; Gonzales et al. 2002).

Risk information

Statement(s) to the effect of

Caution(s) and warning(s)

All products:

If you are pregnant or breastfeeding, consult a health care practitioner prior to use.

Products providing ≥ 0.6 g dried root/hypocotyl, per day:

- ▶ If you are taking antidepressants, consult a health care practitioner prior to use (Dording et al. 2008; Gonzales and Gonzales-Castaneda 2009).
- ▶ If you are taking blood thinners, consult a health care practitioner prior to use (NS 2012).
- ▶ If you have high blood pressure, consult a health care practitioner prior to use (Valentova et al. 2008).

Sexual health products:

If you suffer from any psychological disorder and/or condition such as frequent anxiety or depression, consult a healthcare practitioner prior to use (Brotto 2010; Dording et al. 2008; Gonzales and Gonzales-Castaneda 2009).

Contraindication(s)

No statement required.

Known adverse reaction(s)

No statement required.

Non-medicinal ingredients

Must be chosen from the current NHPD *Natural Health Products Ingredients Database* and must meet the limitations outlined in the database.

Storage conditions

No statement required.

Specifications

- ▶ The finished product specifications must be established in accordance with the requirements



described in the NHPD *Quality of Natural Health Products Guide*.

- ▶ The medicinal ingredient must comply with the requirements outlined in the *Natural Health Products Ingredients Database* (NHPID).

References cited

Brooks NA, Wilcox G, Walker KZ, Ashton JF, Cox MB, Stojanovska L. Beneficial effects of *Lepidium meyenii* (Maca) on physiological symptoms and measures of sexual dysfunction in postmenopausal women are not related to estrogen or androgen content. *Menopause* 2008;15(6):1157-1162.

Brotto LA. The DSM diagnostic criteria for hypoactive sexual desire disorder in women. *Archives of Sexual Behavior* 2010;39(2):221-239.

Dording CM, Fsher L, Papakostas G, Farabaugh A, Sonawalla S, Fava M, Mischoulon D. A double-blind, randomized, pilot dose-finding study of maca root (*L. meyenii*) for the management of SSRI-induced sexual dysfunction. *CNS Neuroscience Therapy and Therapeutics* 2008;14(3):182-191.

Gonzales GF, Gonzales-Castaneda GC. The Methyltetrahydro- β -Carbolines in Maca (*Lepidium meyenii*). *Evidence Based Complementary Alternative Medicine* 2009;6(3):315-316.

Gonzales GF, Cordova A, Vega K, Chung A, Villena A, Gonez C, Costillo S. Effect of *Lepidium meyenii* (Maca) on sexual desire and its absent relationship with serum testosterone levels in adult healthy men. *Andrologia* 2002;34(6):367-372.

McGuffin M, Kartesz JT, Leung AY, Tucker AO, editors. *Herbs of Commerce*. 2nd edition. Silver Spring (MD): American Herbal Products Association; 2000.

Meissner, Kapczynski, Mscisz, Lutomski. Use of Gelatinized Maca (*Lepidium peruvianum*) in Early Postmenopausal Women – a Pilot Study. *International Journal of Biomedical Sciences* 2005;1(1):33-45.

Meissner, Reich-Bilinska, Kedzia. Therapeutic Effects of Pre-Gelatinized Maca (*Lepidium peruvianum* Chacon) used as a non-hormonal alternative to HRT in perimenopausal women – Clinical Pilot study. *International Journal of Biomedical Sciences* 2006;2(2):143-159.

NS 2012. Natural Standard. Maca (*Lepidium meyenii*) Copyright 2012 [Internet]. [Accessed 2012 April 18]. Available from: <http://www.naturalstandard.com>.

Shin BC, Lee MS, Yang EJ, Lim H-S, Ernst E. Maca (*L. meyenii*) for improving sexual function: a systematic review. *BMC Complementary and Alternative Medicine* 2010;10(44):1-6.

USDA 2011: United States Department of Agriculture, Agricultural Research Service, National Genetic Resources Program. Germplasm Resources Information Network (GRIN). [Internet].



National Germplasm Resources Laboratory, Beltsville (MD). [*Lepidium meyenii* Walp. Last updated 2011 June 25; Accessed 2012 April 24]. Available from: http://www.ars-grin.gov/cgi-bin/npgs/html/tax_search.pl

Valentova K, Stejskal D, Bartek J, Dvoráckova S, Kren V, Ulrichova J, Simanek V. Maca (*Lepidium meyenii*) and yacon (*Smallanthus sonchifolius*) in combination with silymarin as food supplements: in vivo safety assessment. *Food and Chemical Toxicology* 2008;46(3):1006-1013.

Vecera R, Orolin J, Skottova N, Kazdova L, Oliyarnik O, Ulrichova J, Simaner V. The Influence of Maca (*Lepidium meyenii*) on Antioxidant Status, Lipid and Glucose Metabolism in Rat. *Plant Foods for Human Nutrition* 2007;62(2):59-63.

Zenico T, Cicero AF, Valmorri L, Mercuriali M, Bercovich E. Subjective effects of *Lepidium meyenii* (Maca) extract on well-being and sexual performances in patients with mild erectile dysfunction: a randomized, double-blind clinical trial. *Andologia* 2009;41(2):95-99.

References reviewed

Baldwin DS. Depression and sexual dysfunction. *British Medical Bulletin* 2001;57: 81-99.

EFSA Compendium of botanicals that have been reported to contain toxic, addictive, psychotropic or other substances of concern; European Food Safety Authority. Parma, Italy. *EFSA Journal* 2009, 7(9): 281. [Accessed 2012 April 19]. Available from: <http://www.efsa.europa.eu/en/supporting/doc/280rax1.pdf>

Gonzales GF, Cordova A, Gonzales C, Chung A, Vega K, Villena A. *Lepidium meyenii* (Maca) improved semen parameters in adult men. *Asian Journal of Andrology* 2001;3(4):301-303.

Gonzales GF, Cordova A, Vega K, Chung A, Villena A, Gonez C. Effect of *Lepidium meyenii* (Maca), a root with aphrodisiac and fertility-enhancing properties, on serum reproductive hormone levels in adult healthy men. *Journal of Endocrinology* 2003;176(1):163-168.

Herraiz T, Galisteo J. Tetrahydro-beta-carboline alkaloids occur in fruits and fruit juices. Activity as antioxidants and radical scavengers. *Journal of Agriculture and Food Chemistry* 2003;51(24):7156-7161.

Laumann, Paik, Rosen. Sexual Dysfunction in the United States: Prevalence and Predictors. *Journal of the American Medical Association* 1999;281(6):537-544.

McCullom MM, Villinski JR, McPhail KL, Craker LE, Gafner S. Analysis of macamides in samples of Maca (*Lepidium meyenii*) by HPLC-UV-MS/MS. *Phytochemical Analysis* 2005;16(6):463-469.

McKay D. Nutrients and botanicals for erectile dysfunction: Examining the evidence. *Alternative medicine review* 2004;9(1):4-16.



Mehta K, Gala J, Bhasake S, Naik S, Modak M, Thakur H, Deo N, Miller S. Comparison of glucosamine sulfate and a polyherbal supplement for the relief of osteoarthritis of the knee. *BMC Complementary and Alternative Medicine* 2007;7(34):1-13.

Passeportsanté. Maca. Fiche complète. [Passeportsanté.net](http://www.passeportsante.net/fr/Solutions/PlantesSupplements/Fiche.aspx?doc=maca_ps); 2011. [Revised 2011 May; Accessed 2012 April 24]. Available from: http://www.passeportsante.net/fr/Solutions/PlantesSupplements/Fiche.aspx?doc=maca_ps

Piacente S, Carbone V, Plaza A, Zampelli A, Pizza C. Investigation of the tuber constituents of maca (*Lepidium meyenii* Walp.). *Journal of Agriculture and Food Chemistry* 2002;50:5621-5625.

Sandoval M, Okuhama NN, Angeles MF, Melchor VV, Condezo AL, Lao L, Miller JSM. Antioxidant activity of the cruciferous vegetable Maca (*Lepidium meyenii*). *Food Chemistry* 2002;79(2):207-213.

Schumacher M et al. Novel perspectives for progesterone in hormone replacement therapy, with special reference to the nervous system. *Endocrine Reviews* 2007;28(4): 387-439.

Sloley BD, Urichuk LJ, Morley P, Durkin J, Shan JJ, Pang PK, Coutts RT. Identification of kaempferol as a monoamine oxidase inhibitor and potential neuroprotectant in extracts of *Ginkgo biloba* leaves. *Journal of Pharmacy and Pharmacology* 2000;52(4):451-459.

Stone M, Ibarra A, Roller M, Zangara A, Stevenson A. A pilot investigation into the effect of maca supplementation on physical activity and sexual desire in sportsmen. *Journal of Ethnopharmacology* 2009;126(3):574-576.

Valentova K, Buckiova D, Kren V, Peknicova J, Ulrichova J, Simanek V. The in vitro biological activity of *Lepidium meyenii* extracts. *Cell Biology and Toxicology* 2006;22(2):91-99.

Valentova K, Ulrichova J. *Smallanthus sonchifolius* and *Lepidium meyenii* – Prospective Andean crops for the prevention of chronic diseases. *Biomedical papers of the Medical Faculty of the University Palacky, Olomouc, Czechoslovakia* 2003;147(2):119-130.

Zheng BL, He K, Kim CH, Rogers L, Shao Y, Huang ZY, Lu Y, Yan SJ, Qien LC, Zheng QY. Effect of a lipidic extract from *Lepidium meyenii* on sexual behavior in mice and rats. *Urology* 2000;55(4):598-602.