



## 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 statements are synonymous. Either term or statement may be selected by the applicant.

#### Date

August 28, 2018

#### Proper name(s), Common name(s), Source material(s)

Table 1. Proper name(s), Common name(s), Source material(s)

Proper name(s)	Common name(s)	Source material(s)		
		Proper name(s)	Part(s)	Preparation(s)
<i>Lepidium meyenii</i>	<ul style="list-style-type: none"> <li>▶ Maca</li> <li>▶ Peruvian-ginseng</li> </ul>	<i>Lepidium meyenii</i>	<ul style="list-style-type: none"> <li>▶ Hypocotyl</li> <li>▶ Root</li> </ul>	Dried

References: Proper name: USDA 2018, McGuffin et al. 2000; Common names: USDA 2018, NS 2012, McGuffin et al. 2000; Source materials: Dording et al. 2008, Meissner et al. 2006.

#### Route of administration

Oral

#### Dosage form(s)

This monograph excludes foods or food-like dosage forms as indicated in the Compendium of Monographs Guidance Document.

Acceptable dosage forms for the age category listed in this monograph and specified route of administration are indicated in the Compendium of Monographs Guidance Document.



## Use(s) or Purpose(s)

- ▶ Source of/Provides antioxidants (Brooks et al. 2008; Vecera et al. 2007).
- ▶ 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).

The following combined use(s) or purpose(s) is/are also acceptable:

- ▶ Helps support healthy mood balance during menopause and 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).

## Dose(s)

### Sub-population(s)

Adults 18 years and older

### Quantity(ies)

Methods of preparation: Dry, Powder, Non-Standardised Extracts (Dry extract, Tincture, Fluid Extract, Decoction, Infusion)

#### *Antioxidant*

Not to exceed 3 grams dried root/hypocotyl, per day (Brooks et al. 2008; Vecera et al. 2007)

#### *Mood balance during menopause*

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

#### *Sexual health*

3 - 3.5 grams dried root/hypocotyl, 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)

### Direction(s) for use

No statement required.



## **Duration(s) of use**

*Products providing 0.6 to 3 g dried root/hypocotyl, per day*

Consult a health care practitioner/health care provider/health care professional/doctor/physician for use beyond 3 months (Zenico et al. 2009; Dording et al. 2008; Meissner et al. 2006; Gonzales et al. 2002).

*Products providing more than 3 g dried root/hypocotyl, per day*

Consult a health care practitioner/health care provider/health care professional/doctor/physician for use beyond 6 weeks (Brooks et al. 2008).

## **Risk information**

### **Caution(s) and warning(s)**

*All products*

Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you are pregnant or breastfeeding.

*Products providing 0.6 g or more dried root/hypocotyl, per day*

- ▶ Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you have high blood pressure (Valentova et al. 2008).
- ▶ Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you are taking antidepressants or blood thinners (NS 2012; Gonzales and Gonzales-Castaneda 2009; Dording et al. 2008).

*Sexual health*

Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you suffer from any psychological disorder and/or condition such as frequent anxiety or depression (Brotto 2010; Gonzales and Gonzales-Castaneda 2009; Dording et al. 2008).

### **Contraindication(s)**

No statement required.



### **Known adverse reaction(s)**

No statement required.

### **Non-medicinal ingredients**

Must be chosen from the current Natural Health Products Ingredients Database (NHPID) 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 Natural and Non-prescription Health Products Directorate (NNHPD) Quality of Natural Health Products Guide.
- ▶ The medicinal ingredient must comply with the requirements outlined in the 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- $\beta$ -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 2018 June 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 2018: 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 2018 June 18]. Available from: [http://www.ars-grin.gov/cgi-bin/npgs/html/tax\\_search.pl](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.

McCollom 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.

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 (*Lepidum 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.