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)**


- 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)**

**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**

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


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.


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.


References reviewed


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


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.