



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"> ▶ Maca ▶ Peruvian-ginseng 	<i>Lepidium meyenii</i>	<ul style="list-style-type: none"> ▶ Hypocotyl ▶ Root 	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.

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