NATURAL HEALTH PRODUCT

AMERICAN GINSENG

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

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

Date: July 7, 2015

Proper name(s):

*Panax quinquefolius* L. (Araliaceae) (USDA 2005)

Common name(s):


Source material(s):

Root (PPRC 2010; Lust 1974; Wren 1956)

Note: *Panax quinquefolius* is an endangered plant in the wild; thus only the roots from cultivated plants are acceptable source material. See Specifications for further details.

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:

- Used in Traditional Chinese Medicine (TCM) for deficiency of *qi* and *yin*, internal heat, cough, bloody phlegm, fire in the deficiency syndrome, dysphoria and tiredness, dry and thirsty mouth and throat (PPRC 2010).
- Used in Herbal Medicine as supportive therapy for the promotion of healthy glucose levels (Dascalu et al. 2007; PPRC 2010; Vuksan et al. 2000a; Vuksan et al. 2000b; Vuksan et al. 2000c).
- Traditionally used in Herbal Medicine to help relieve nervousness (as mild sedative) (Bartram 1998; Ellingwood 1998).
- Traditionally used in Herbal Medicine to help relieve nervous dyspepsia / to help digestion in cases of nervousness and/or stress (Bartram 1998; Felter and Lloyd 1983; Wren 1956).
- Used in Herbal Medicine as an adaptogen to help maintain a healthy immune system (Upton 2012; Godfrey et al. 2010; Assinewe 2001; Bartram 1998).

Dose(s):

*Glucose levels; Mild sedative; Nervousness; Immune System*

Dry, powder, decoction, infusion, extract dry, extract liquid, tincture, fluid extract:
0.5 - 12 Grams dried root, per day (Bartram 1998; Felter and Lloyd 1983; Wren 1956).

*TCM*
Decoction:
2.4 - 9 Grams dried root, per day (PPRC 2010; Bensky and Gamble 1993).

Duration(s) of use:

No statement required.

Risk information: Statement(s) to the effect of:

Caution(s) and warning(s):

- If you are taking blood thinners, or digoxin, consult a health care practitioner prior to use (Brinker 2010; Elmer et al. 2007; Dasgupta et al. 2005; Yuan et al. 2004).
- If you have diabetes, consult a health care practitioner prior to use (Dascalu et al. 2007; Brinker 2010; Vuksan et al. 2000a; Vuksan et al. 2000b; Vuksan et al. 2000c).
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 that database.

Specifications:
- The finished product specifications must be established in accordance with the requirements described in the Natural and Non-Prescription Health Products Directorate Quality of Natural Health Products Guide.
- The medicinal ingredient must comply with the requirements outlined in the NHPID. Proof of sale or permit must be available for possession of the cultivated *Panax quinquefolius* because the wildlife species is endangered:
  - *Panax quinquefolius* is protected under the federal *Species at Risk Act* (SARA). Under section 32(2) of this Act, no person shall possess, collect, buy, sell or trade an individual of a wildlife species that is listed as an extirpated species, an endangered species or a threatened species, or any part or derivative of such an individual (JC 2015).
  - *Panax quinquefolius* is protected by the Quebec *Act Respecting Threatened or Vulnerable Species*. Under this Act, it is prohibited to possess, trade, or harm this species, or to disturb its habitat (EC 2015).
- The medicinal ingredient may comply with the specifications outlined in the American Ginseng, Powdered American Ginseng monographs published in the U.S. Pharmacopoeia (USP 38).

References cited:


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References reviewed:


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López MV, Cuadrado MP, Ruiz-Poveda OM, Del Fresno AM, Accame ME. Neuroprotective effect of individual ginsenosides on astrocytes primary culture. Biochimica et Biophysica Acta 2007;1770(9):1308-1316.


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Wren RC. Potter’s Cyclopedia of Botanical Drugs and Preparations. London (GB): Potter and Clark; 1907.


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