

## NATURAL HEALTH PRODUCT

### PANAX GINSENG

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

February 23, 2024

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

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

Proper name(s)	Common name(s)	Source information		
		Source material(s)	Part(s)	Preparation(s)
<i>Panax ginseng</i>	<ul style="list-style-type: none"> <li>• Asian ginseng</li> <li>• Chinese ginseng</li> <li>• Hong shen</li> <li>• Korean ginseng</li> <li>• Korean red ginseng</li> <li>• Oriental ginseng</li> <li>• Panax ginseng</li> <li>• Red ginseng</li> <li>• Ren shen</li> </ul>	<i>Panax ginseng</i>	<ul style="list-style-type: none"> <li>• Root</li> <li>• Rootlet</li> </ul>	Dry

References: Proper name: USDA 2024; Gardner and McGuffin 2013; Common names: USDA 2024; USP-NF 2023; PPRC 2015; Gardner and McGuffin 2013; Vuksan et al. 2008; Reay et al. 2006; Kim et al. 2005; Sünram-Lea et al. 2005; WHO 1999; Source information: USP-NF 2023; PPRC 2015; Ph. Eur 2008; Vuksan et al. 2008; Sievenpiper et al. 2006; ESCOP 2003; WHO 1999; Bradley 1992; BHP 1983; Wren 1907.

#### 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 oral use are indicated in the dosage form drop-down list of the web-based Product Licence Application form for Compendial applications.

## Use(s) or Purpose(s)

- (Used in Herbal Medicine as) supportive therapy for the promotion of healthy glucose levels (Vuksan et al. 2008; Sievenpiper et al. 2006; Williamson 2003; Tetsutani et al. 2000; WHO 1999; Sotaniemi et al. 1995).
- (Used in Herbal Medicine to) help(s) support cognitive function and/or reduce mental fatigue (in cases of mental stress) (Reay et al. 2006; Reay et al. 2005; Sünram-Lea et al. 2005; Kennedy et al. 2004; ESCOP 2003; Kennedy et al. 2002; Scholey and Kennedy 2002; Kennedy et al. 2001; Sorensen and Sonne 1996; Bradley 1992; D'Angelo et al. 1986; BHP 1983).
- Helps support cognition (Reay et al. 2006; Reay et al. 2005; Sünram-Lea et al. 2005; Kennedy et al. 2004; ESCOP 2003; Kennedy et al. 2002; Scholey and Kennedy 2002; Kennedy et al. 2001; Sorensen and Sonne 1996; Bradley 1992; D'Angelo et al. 1986; BHP 1983).
- (Used in Herbal Medicine to) help(s) enhance physical capacity/performance (in cases of physical stress) (Kim et al. 2005; ESCOP 2003; Gross et al. 2002; WHO 1999; Gross et al. 1995; Sotaniemi et al. 1995; Schepdael 1993).
- Used in Herbal Medicine as an adaptogen to help increase energy and resistance to stress (e.g. in case of mental and physical fatigue related to stress) (Winston and Maimes 2007, Bone 2003, Hoffman 2003, Blumenthal et al. 2000, WHO 1999, Bradley 1992).
- Used in Traditional Chinese Medicine (TCM) to reinforce *qi*, benefit the spleen and lung, relieve symptoms of thirst due to impairment of body fluids and internal heat (PPRC 2015; Bensky et al. 2004, Chen and Chen 2004).

## Notes

- The above uses can be combined on the product label if from the same traditional or non-traditional system of medicine (e.g. Used in Herbal Medicine to help support cognitive function and/or reduce mental fatigue and as an adaptogen to help increase energy and resistance to stress.)
- **For multi-ingredient products:**
  - To prevent the product from being represented as a “traditional medicine”, any indicated traditional use claim must refer to the specific medicinal ingredient(s) and recognized system of medicine from which the claim originates when 1) both the traditional and modern claims are present or 2) when claims original from multiple systems of traditional medicine (e.g. Panax Ginseng is used in Traditional Chinese Medicine to reinforce *qi*, benefit the spleen and lung, relieve symptoms of thirst due to impairment of body fluids and internal heat ).



- When ALL of the medicinal ingredients (MIs) in the product are used within the SAME identified system of traditional medicine AND the product makes ONLY traditional claims, listing of MIs in the traditional claim(s) is not required.

### **Dose(s)**

#### **Subpopulation(s)**

Adults 18 years and older

#### **Quantity(ies)**

*Glucose levels; Cognitive function/cognition; Mental stress; Physical stress; Adaptogen*

Methods of preparation: Standardized extracts (Dry extract)

200 - 600 milligrams of extract, per day; standardized to 4 - 7% total ginsenosides; Not to exceed 9 grams of dried root/rootlet, per day (Vuksan et al. 2008; Reay et al. 2006; Sievenpiper et al. 2006; Reay et al. 2005; Sunram-Lea et al. 2005; Kennedy et al. 2004; ESCOP 2003; Kennedy et al. 2002; Scholey and Kennedy 2002; Engels et al. 2001; Kennedy et al. 2001; Scaglione et al. 2001; Blumenthal et al. 2000; Tetsutani et al. 2000; Engels et al. 1996; Scaglione et al. 1996; Gross et al. 1995; Scaglione et al. 1994; Scaglione et al. 1990; Petkov and Mosharrof 1987; D'Angelo et al. 1986; Soldati and Sticher 1980).

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

0.5 - 9 grams dried root/rootlets, per day (Vuksan et al. 2008; Reay et al. 2006; Sievenpiper et al. 2006; Reay et al. 2005; Sunram-Lea et al. 2005; Kennedy et al. 2004; ESCOP 2003; Kennedy et al. 2002; Scholey and Kennedy 2002; Engels et al. 2001; Kennedy et al. 2001; Scaglione et al. 2001; Blumenthal et al. 2000; Engels et al. 1996; Scaglione et al. 1996; Gross et al. 1995; Scaglione et al. 1994; Scaglione et al. 1990; Petkov and Mosharrof 1987; D'Angelo et al. 1986; Soldati and Sticher 1980).

#### *Traditional Chinese Medicine*

Methods of preparation: Decoction, Decoction concentrate

3 - 10 grams dried root, per day (PPRC 2015; Bensky et al. 2004, Chen and Chen 2004).

Methods of preparation: Powder (unextracted)

0.5 - 4 grams dried root, per day (PPRC 2015, Bensky et al. 2004, Chen and Chen 2004).

## Direction(s) for use

No statement required.

## Duration(s) of use

**Ask a health care practitioner/health care provider/health care professional/doctor/physician** for use beyond 3 months (Mills and Bone 2005; Blumenthal et al. 2000; Bradley 1992).

## Risk information

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

- **Ask a health care practitioner/health care provider/health care professional/doctor/physician before use** if you are pregnant or breastfeeding.
- **Ask a health care practitioner/health care provider/health care professional/doctor/physician before use** if you have diabetes (Brinker 2010; Vuksan et al. 2008; Seely et al. 2008; Sievenpiper et al. 2006; ESCOP 2003; Tetsutani et al. 2000; Sotaniemi et al. 1995; Chin 1991).
- **Ask a health care practitioner/health care provider/health care professional/doctor/physician before use** if you are taking antidepressant medication, blood thinners or digoxin (Brinker 2010; Lee et al. 2008a; Dasgupta and Reyes 2005; Janetzki and Morreale 1997; Gonzalez-Sejjo et al. 1995; Shader and Greenblatt 1988; Jones and Runikis 1987; Shader and Greenblatt 1985).

### Contraindication(s)

#### *Traditional Chinese Medicine*

**Do not use** in cases of yin deficiency with heat signs, heat excess, or in the absence of significant *qi* deficiency (Bensky et al. 2004).

### Known adverse reaction(s)

**Stop use and ask a health care practitioner/health care provider/health care professional/doctor/physician** if you experience insomnia, anxiety or headaches (Lee et al. 2008b; Vuksan et al 2008; de Andrade et al.2007; Sievenpiper et al. 2006; Coon and Ernst 2002; Ellis and Reddy 2002; Scaglione et al. 2001; Siegel 1979).

## 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

Must be established in accordance with the requirements described in the *Natural Health Products Regulations*.

### 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.

### EXAMPLE OF PRODUCT FACTS:

Consult the Guidance Document, [Labelling of Natural Health Products](#) for more details.

<b>Product Facts</b>	
<b>Medicinal ingredient</b> in each capsule <i>Panax ginseng</i> (Asian ginseng – root) extract Standardized to 4 – 7% total ginsenosides	XX mg
<b>Uses</b>	
<ul style="list-style-type: none"> <li>• (Used in Herbal Medicine as) supportive therapy for the promotion of healthy glucose levels.</li> <li>• (Used in Herbal Medicine to) help support cognitive function and/or reduce mental fatigue (in cases of mental stress).</li> <li>• Helps support cognition.</li> <li>• (Used in Herbal Medicine to) enhance physical capacity/performance (in cases of physical stress.</li> <li>• Used in Herbal Medicine as an adaptogen to help increase energy and resistance to stress (e.g. in case of mental and physical fatigue related to stress).</li> <li>• Used in Traditional Chinese Medicine (TCM) to reinforce <i>qi</i>, benefit the spleen and lung, relieve symptoms of thirst due to impairment of body fluids and internal heat.</li> </ul>	
<b>Warnings</b>	
<b>If applicable:</b>	
<b>Allergens: food allergen, gluten (gluten source), sulphites</b>	
<b>Contains aspartame</b>	
<b>Do not use</b> in cases of yin deficiency with heat signs, heat excess, or in the absence of significant <i>qi</i> deficiency.	
<b>Ask a health care practitioner before use if</b> • you are pregnant or breastfeeding • you have diabetes • you are taking antidepressant medication, blood thinners or digoxin.	
<b>Stop use and ask a health care practitioner if</b> you experience insomnia, anxiety or headaches.	
<b>Directions</b>	
Adults 18 years and older: • Take X capsule(s), X time(s) a day • Ask a health care practitioner for use beyond 3 months.	
<b>Other information</b>	

(Add storage information)

**Non-medicinal ingredients**

List all NMIs

**Questions? (Call) 1-XXX-XXX-XXXX**

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