

NATURAL HEALTH PRODUCT

AMERICAN GINSENG - *PANAX QUINQUEFOLIUS*

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 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 on the label.

Date November 29, 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 quinquefolius</i>	<ul style="list-style-type: none">American ginsengOccidental ginsengSangShangXi yang shen	<i>Panax quinquefolius</i>	Root	Dry

References: Proper name: USDA 2024; Common names: USDA 2024; PPRC 2020; Gardner and McGuffin 2013; Source information: PPRC 2020; Lust 1974; Wren 1956.

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 Traditional Chinese Medicine (TCM) for deficiency of *qi* and *yin*, internal heat, cough, fire in the deficiency syndrome, dysphoria and tiredness, dry and thirsty mouth and throat (PPRC 2020).
- Used in Herbal Medicine as supportive therapy for the promotion of healthy (blood) glucose/sugar levels (Dascalu et al. 2007; Vuksan et al. 2000a,b,c).
- (Traditionally) used in Herbal Medicine to help relieve restlessness and/or nervousness (nervine/calmative) (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; Bartram 1998).
- Used in Herbal Medicine as an adaptogen to help increase energy and resistance to stress over time (e.g. in case of mental and physical fatigue related to stress) (Upton 2012; Winston and Maimes 2007).

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 digestion in cases of nervousness or stress and as supportive therapy for the promotion of healthy glucose levels).
- **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 traditional system of medicine from which the claim originates when 1) both traditional and modern claims are present or 2) when claims originate from multiple systems of traditional medicine (e.g., American ginseng is used in Traditional Chinese Medicine (TCM) for deficiency of *qi* and *yin*, internal heat, cough, fire in the deficiency syndrome, dysphoria and tiredness, dry and thirsty mouth and throat).
 - 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; Restlessness/Nervousness; Nervous dyspepsia/Digestion

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

0.5 – 12 grams dried root, per day (Bartram 1998; Felter and Lloyd 1983; Wren 1956).

***Note:** Solvents allowed for the method of preparation “Non-Standardized extracts (Dry extract)” as part of this monograph are ethanol and/or water only.

Adaptogen – energy and resistance to stress; Adaptogen – immune system

Methods of preparation: Dry, Powdered, Non-Standardized Ethanolic Extracts (Dry extract, Tincture, Fluid extract)

1 – 3 grams dried root, per day (Upton 2012; Winston and Maimes 2007).

Adaptogen – energy and resistance to stress

Methods of preparation: Non-Standardized Aqueous Extracts (Dry extract, Decoction, Decoction concentrate, Infusion, Infusion concentrate)

6 – 9 grams dried root, per day; Not to exceed 3 grams per single dose (Winston and Maimes 2007).

TCM

Methods of preparation: Decoction, Decoction concentrate

2.4 – 9 grams dried root, per day (PPRC 2020; Bensky et al. 2004).

Direction(s) for use

No statement required.

Duration(s) of use

No statement required.

Risk information

Caution(s) and warning(s)

All products

- **Ask a health care practitioner/health care provider/health care professional/doctor/physician before use** if you are taking blood thinners or digoxin (Brinker 2010; Dasgupta et al. 2007; Elmer et al. 2007; Yuan et al. 2004).
- **Ask a health care practitioner/health care provider/health care professional/doctor/physician before use** if you have diabetes (Brinker 2010; Dascalu et al. 2007; Vuksan et al. 2000a,b,c).

All products except Glucose levels and Adaptogen – immune system

Ask a health care practitioner/health care provider/health care professional/doctor/physician if symptoms persist or worsen.

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

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.

Product Facts	
Medicinal ingredient in each capsule	
<i>Panax quinquefolius</i> (American ginseng) X:1 extract Equivalent to YY g dried root	XX mg
Uses	
<ul style="list-style-type: none"> Used in Herbal Medicine as supportive therapy for the promotion of healthy glucose levels. Traditionally used in Herbal Medicine to help relieve restlessness and nervousness. Traditionally used in Herbal Medicine to help digestion in cases of nervousness or stress. 	
Warnings	
If applicable¹: Allergens: food allergen, gluten (gluten source), sulphites Contains aspartame	
Ask a health care practitioner before use if • you are taking blood thinners or digoxin • you have diabetes.	
Ask a health care practitioner if symptoms persist or worsen.	
Directions	
Adults 18 years and older: Take X capsule(s), X time(s) per day.	
Other information	
(Add storage information).	
Non-medicinal ingredients	
List all NMIs.	
Questions? (Call) 1-XXX-XXX-XXXX	

¹This section can be removed from the table if the product contains no allergen or aspartame.

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