



NATURAL HEALTH PRODUCT

ASTRAGALUS – *ASTRAGALUS MEMBRANACEUS*

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 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

May 30, 2025

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>Astragalus membranaceus</i> | <ul style="list-style-type: none"> • Astragalus • Huangqi • Huang qi • Membranaceus milk vetch • Membranous milk-vetch • Milk vetch root • Mo jia huang qi | <i>Astragalus membranaceus</i> | Root | Dry |

References: Proper name: USDA 2024; Common names: PPRC 2020; Gardner and McGuffin 2013; HKCMM 2008; Bensky et al. 2004; Source information: PPRC 2020; Bensky et al. 2004; Hoffman 2003.

Route of administration

Oral

Dosage form(s)

This monograph excludes foods or food-like dosage forms such 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) to tonify the spleen and lungs in cases of qi deficiency with a lack of appetite, fatigue, and diarrhea (PPRC 2020; Benksy et al. 2004).
- Used in Traditional Chinese Medicine (TCM) to augment the protective *qi* and stabilize the exterior in cases of deficiency with spontaneous sweating (PPRC 2020; Benksy et al. 2004).
- Used in Herbal Medicine to help maintain a healthy immune system (Winston and Kuhn 2008; Mills and Bone 2005; Hoffman 2003; Upton 1999).
- 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) (Winston and Maimes 2007; Bone 2003).

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 maintain a healthy immune system and as an adaptogen to help increase energy and resistance to stress over time).
- **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., Astragalus is traditionally used in Traditional Chinese Medicine to augment the protective *qi* and stabilize the exterior in cases of deficiency with spontaneous sweating).
 - 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)

Traditional Chinese Medicine

Methods of preparation: Dry, Powdered, Decoction, Decoction concentrate

9 – 30 grams dried root, per day (PPRC 2020; Benksy et al. 2004).

Note: Dried or powdered root should be prepared as a decoction (see direction for use).



Maintenance of healthy immune system

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

2 – 4.8 grams dried root, per day (Mills and Bone 2005; Hoffman 2003).

***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

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

2 – 4.8 grams dried root, per day (Bone 2003; Hoffman 2003)

Direction(s) for use

Traditional Chinese Medicine

Dry or powdered root

Place the dried (powdered) roots in a pot and add enough water to submerge them. Boil for 20-25 minutes, strain and drink (Cao 1996).

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 pregnant or breastfeeding.

Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you have an autoimmune disorder (Brinker 2010; Upton 1999).



Contraindication(s)

Traditional Chinese Medicine

Do not use if you have exterior excess, stagnation, *yin* deficiency or excess heat (Bensky et al. 2004; Chen and Chen 2004).

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.

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|---|
| Product Facts |
| Medicinal ingredient in each capsule <i>Astragalus membranaceus</i> (Astragalus – root) X:1 extract XX mg Equivalent to YY g of dried root |
| Uses <ul style="list-style-type: none"> • Used in Herbal Medicine to help maintain a healthy immune system. • Used in Herbal Medicine as an adaptogen to help increase energy and resistance to stress over time. |
| Warnings |
| If applicable¹: Allergens: food allergen, gluten (gluten source), sulphites Contains aspartame |
| Ask a health care practitioner before use if • you are pregnant or breastfeeding • you have an autoimmune disorder. |
| 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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Cao C. Chinese Drug Pharmaceutics: Chinese Collegiate Textbooks for Medical Institutions of Higher Learning. Beijing (China): Shanghai Science and Technology Publisher (in Chinese); 1996.

Chen JK, Chen TT. Chinese Medical Herbology and Pharmacology. Crampton L, editor. City of Industry (CA): Art of Medicine Press Inc.; 2004.



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