

ASTRAGALUS

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. It is a referenced document to be used as a labelling standard.

Note: 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 are synonyms or that the statements are synonymous. Either term or statement may be selected by the applicant.

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Proper name(s): *Astragalus membranaceus* (Fisch. ex. Link) Bunge
(Fabaceae/Leguminosae) (USDA 2006)

Common name(s):

- ▶ Astragalus (McGuffin et al. 2000)
- ▶ Membranous milkvetch (McGuffin et al. 2000)
- ▶ Mo jia huang qi (McGuffin et al. 2000)
- ▶ Huang qi (HKCMM 2008; McGuffin et al. 2000)
- ▶ Milkvetch root (PPRC 2000; Bensky and Gamble 1986)

Source material(s): Root (Hoffman 2003; PPRC 2000; Bensky and Gamble 1986)

Route(s) of administration: Oral

Dosage form(s): The acceptable pharmaceutical dosage forms include, but are not limited to chewables (eg. gummies, tablets), caplets, capsules, strips, lozenges, powders or liquids where the dose is measured in drops, teaspoons or tablespoons. 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:

- ▶ Traditionally used in Traditional Chinese Medicine (TCM) to tonify the spleen and augment the *qi* (vital energy): for spleen

deficiency presenting with the lack of appetite, fatigue, and diarrhea. (PPRC 2000; Bensky and Gamble 1986).

- ▶ Traditionally used in TCM to tonify the lungs and is used for frequent colds (PRC 1998; Bensky and Gamble 1986).
- ▶ Traditionally used in TCM to augment the protective *qi* and stabilize the exterior: for deficiency with spontaneous sweating (PPRC 2000; Bensky and Gamble 1986).
- ▶ Used in Herbal Medicine to help maintain a healthy immune system (Winston and Kuhn 2008; Mills and Bone 2005; Hoffman 2003; Upton 1999).

Dose(s):

TCM:

Preparations equivalent to 9-30 g dried, cut root prepared as a decoction, per day (PPRC 2000; Bensky and Gamble 1986).

Directions for use:

Add water to 3-5 cm higher than the surface of the dried root, let sit for 60 minutes. Boil for 20-25 minutes, remove and drink.

To make an additional preparation from the same dried root, add fresh water to 1-2 cm higher than surface of the dried root, boil for 15-20 minutes, remove and drink (Cao 1996).

Maintenance of healthy immune system:

Preparations equivalent to 2-4.8 g dried root, per day (Mills and Bone 2005; Hoffman 2003)

See Appendix 1 for examples of dosage preparations, frequencies of use and directions for use, according to cited references. The purpose of Appendix 1 is to provide guidance to industry.

Duration of use: No statement required.

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

Caution(s) and warning(s):

- ▶ Consult a health care practitioner prior to use if you have an autoimmune disorder (Brinker 2001, Upton 1999)
- ▶ Consult a health care practitioner prior to use if you are pregnant or breastfeeding.

Contraindication(s): According to TCM, do not use in cases of “... exterior excess, *qi* stagnation, damp obstruction, food stagnation, *yin* deficiency with heat signs, or skin lesions in their early stages or where there is a heat toxin.”(Bensky and Gamble 1986).

Known adverse reaction(s): No statement required.

Non-medicinal ingredients: Must be chosen from the current NHPD *Natural Health Products Ingredients Database* and must meet the limitations outlined in the database.

Specifications:

- ▶ The finished product must comply with the minimum specifications outlined in the current NHPD *Compendium of Monographs*.
- ▶ The medicinal ingredient may comply with the specifications outlined in the British Pharmacopoeia (BP) monographs Astragalus root for use in THM and Processed Astragalus Root for use in THMP.

References:

Bensky D, Gamble A. 1986. Chinese Herbal Medicine: Materia Medica. Seattle (WA): Eastland Press, Inc.

BP 2009: British Pharmacopoeia Commission. 2008. British Pharmacopoeia 2009, Volume II. London (GB): The Stationary Office on behalf of the Medicines and Healthcare products Regulatory Agency (MHRA).

Brinker F. 2001. Herb Contraindications and Drug Interactions, 3rd Edition. Sandy (OR): Eclectic Medical Publications.

Cao C. 1996. Chinese Drug Pharmaceutics: Chinese Collegiate Textbooks for Medical Institutions of Higher Learning. Beijing (China): Shanghai Science and Technology Publisher (in Chinese).

HKCMM 2008: Hong Kong Chinese Materia Medica Standards, Volume 1. Wanchai (HK): Chinese Medicine Division, Government of the Hong Kong Special Administrative Region, the People's Republic of China.

Hoffmann D. 2003. Medical Herbalism: The Science and Practice of Herbal Medicine. Rochester (VT): Healing Arts Press.

Mills S, Bone K. 2005. The Essential Guide to Herbal Safety. St. Louis (MO): Elsevier Churchill Livingstone.

McGuffin M, Kartesz JT, Leung AY, Tucker AO, editors. 2000. Herbs of Commerce, 2nd edition. Silver Spring (MD): American Herbal Products Association.

Peirce A. Practical Guide to Natural Medicines. 1999. New York (NY): The Stonesong Press, Inc.

PPRC 2000: Pharmacopoeia of the People's Republic of China, Volume 1, English edition 2000. Beijing (CN): The State Pharmacopoeia Commission of the People's Republic of China.

PRC 1998: The People's Republic of China. Comprehensive Chinese Materia Medica, 1st version. Editorial board of Comprehensive Chinese Materia Medica of State Administration of Traditional Chinese Medicine of the People's Republic of China. Shanghai (China): Shanghai Science and Technology Publishing House; 1998 (in Chinese).

Upton R, editor. 1999. American Herbal Pharmacopoeia and Therapeutic Compendium: Astragalus Root. Santa Cruz (CA): American Herbal Pharmacopoeia.

USDA 2006: United States Department of Agriculture, Agricultural Research Service, National Genetic Resources Program. Germplasm Resources Information Network (GRIN). *Astragalus*. National Germplasm Resources Laboratory, Beltsville (MD). [Accessed 2010-07-06]. Available at http://www.ars-grin.gov/cgi-bin/npgs/html/tax_search.pl

Winston D, Kuhn MA. 2008. Winston and Kuhn's Herbal Therapy and Supplements: A Scientific and Traditional Approach, 2nd edition. Philadelphia (PA): Lippincott Williams and Wilkins.

Appendix 1: Examples of dosage preparations, frequencies of use and directions for use

Dried root:

Liquid extract: 2.25-4.25 g dried equivalent, per day
(1:2, 4.5-8.5 ml) (Mills and Bone 2005)

Tincture: 0.8-1.6 g dried equivalent, 3 times per day
(1:5, 40% alcohol, 4-8 ml) (Hoffman 2003)