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.

Date: July 7, 2010

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 (HKCM M 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; Benksy and Gamble 1986).

- Traditionally used in TCM to tonify the lungs and is used for frequent colds (PRC 1998; Benksy and Gamble 1986).
- Traditionally used in TCM to augment the protective qi and stabilize the exterior: for deficiency with spontaneous sweating (PPRC 2000; Benksy 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; Benksy 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).

**Maintainance 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:


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)