TRIBULUS - TRIBULUS TERRESTRIS

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 the statements are synonymous. Either term or statement may be selected by the applicant.

Date
January 22, 2013

Proper name(s)

*Tribulus terrestris* L. (1753) (Zygophyllaceae) (USDA 2011; PPRC 2010; API 2001; McGuffin et al. 2000)

Common name(s)

- Tribulus (USDA 2011; Bensky et al. 2004; McGuffin et al. 2000)
- Puncturevine caltrop (PPRC 2010; McGuffin et al. 2000)
- Caltrop (USDA 2011; Bensky et al. 2004; API 2001)
- Gokshura (API 2001; McGuffin et al. 2000)
- Gokshura (API 2001; McGuffin et al. 2000)
- Puncturevine (USDA 2011; Bensky et al. 2004)
- Jí lí (USDA 2011; PPRC 2010; Bensky et al. 2004; Chen and Chen 2004)

Source material(s)

- fruit (PPRC 2010; Bensky et al. 2004; Chen and Chen 2004; API 2001; Kapoor 2001)
- root (API 2001)

Route(s) of administration

oral
Dosage form(s)

- The acceptable pharmaceutical dosage forms include, but are not limited to capsules, chewables (e.g. gummies, tablets), liquids, powders, strips or tablets.
- 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 Ayurveda as Mutrala (diuretic) (Premila 2006; API 2001; Kapoor 2001).
- Traditionally used in Ayurveda as Vrsya (aphrodisiac) for men (Paranjpe 2005; API 2001).
- Traditionally used in Ayurveda to help relieve Arsa (haemorrhoids) (API 2001).
- Traditionally used in Ayurveda to help relieve Mutrakrcchra (difficult/painful urination) (Khare 2004; API 2001).
- Used in Traditional Chinese Medicine (TCM) for headache and dizziness, distending pain in the chest and the hypochondrium, acute mastitis, red eyes and nebula, itching caused by rubella (PPRC 2010).
- Used in Traditional Chinese Medicine (TCM) to calm the Liver and anchor the yang: for headache, vertigo, or dizziness from ascendant Liver yang (Bensky et al. 2004).
- Used in Traditional Chinese Medicine (TCM) to dispel wind and stop itching: for any kind of skin lesion with significant itching, such as hives (Bensky et al. 2004).
- Used in Traditional Chinese Medicine (TCM) to dispel wind-heat and brightens the eyes: for red, swollen, and painful eyes as well as increased tearing (Bensky et al. 2004).
- Used in Traditional Chinese Medicine (TCM) to dredge the Liver qi to smooth its flow while dispersing constraint and clumping: for pain and distention in the chest or flanks, irregular menstruation, or insufficient lactation, from constrained Liver qi (Bensky et al. 2004).
- Used in Traditional Chinese Medicine (TCM) to pacify the Liver, active blood and dispel wind, improve vision, and relieve itching (PPRC 2010).

Note
A claim for traditional use must include the term “Traditional Chinese Medicine”, “Ayurveda”, or “Ayurvedic medicine”.

**Dose(s)**

**Subpopulation(s)**

adults ($\geq 19$ years)

**Quantity(ies)**

**TCM products**

Decoction:
6-10 g dried fruit, per day (PPRC 2010; Bensky et al. 2004; Chen and Chen 2004)

**Ayurveda products**

*Arsa (haemorrhoid)*

Decoction:
20-30 g dried fruit, per day (API 2001)

Powder:
3-6 g dried fruit, per day (API 2001)

*Mutrala (diuretic), Mutrakrcchra (painful urination) and Vrsya (aphrodisiac)*

Decoction:
- 20-30 g dried fruit, per day (API 2001)
- 20-30 g dried root, per day (API 2001)

Powder:
3-6 g dried fruit, per day (API 2001)

**Duration(s) of use**

Statement(s) to the effect of

*Mutrala (diuretic):*
For occasional use only (APhA 2002; CPhA 2002).

**Risk information**

Statement(s) to the effect of

**Caution(s) and warning(s)**

All products except *Vrsya (aphrodisiac):*
- If symptoms persist or worsen, consult a health care practitioner.
- If you are pregnant, consult a health care practitioner prior to use (Chen and Chen 2004).
TCM products:
In case of qi or blood deficiency, consult a health care practitioner prior to use (Bensky et al. 2004).

**Contraindication(s)**

TCM products:
- If you have hypotension, do not use this product (Chen and Chen 2004).
- If you have a liver deficiency, do not use this product (Bensky et al. 2004).

**Known adverse reaction(s)**

All products:
Hypersensitivity/allergy has been known to occur (Bensky et al. 2004); in which case, discontinue use.

All products except *Mutrala* (diuretic):
Diuretic effect may occur.

**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 specifications must be established in accordance with the requirements described in the NHPD *Quality of Natural Health Products Guide*.
- The medicinal ingredient must comply with the requirements outlined in the *Natural Health Products Ingredients Database* (NHPID).

**References cited**


References reviewed


Adimoelja A, Setiawan L, Djiojotananjo T. Tribulus terrestris (protodioscin) in the treatment of male infertility with idiopathic ologiasthenoteratozoospermia 1995 [Internet]. Academic Hospital Dr. Soetomo and Airlangga University, Surabaya, Indonesia in First International Conference of


Brinker 2010: Brinker F. Final updates and additions for Herb Contraindications and Drug Interactions, 3rd edition, including extensive Appendices addressing common problematic conditions, medications and nutritional supplements, and influences on Phase I, II & III metabolism with new appendix on botanicals as complementary adjuncts with drugs. [Internet]. Sandy (OR): Eclectic Medical Publications. [Updated July 13, 2010; Accessed 2012 April 30]. Available from: http://www.eclecticherb.com/emp/updatesHCDI.html


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