

NATURAL HEALTH PRODUCT

TRIBULUS – *TRIBULUS TERRESTRIS*

This monograph is intended to serve as a guide to industry for the preparation of Product License 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 statements are synonymous. Either term or statement may be selected by the applicant.

Date

February 25, 2019

Proper name(s), Common name(s), Source material(s)

Table 1. Proper name(s), Common name(s), Source material(s)

Proper name(s)	Common name(s)	Source material(s)		
		Proper name(s)	Part(s)	Preparation(s)
<i>Tribulus terrestris</i>	<ul style="list-style-type: none"> ▶ Caltrop ▶ Cat's-head ▶ Common dubbletjie ▶ Devil's-thorn ▶ Devil's-weed ▶ Goathead ▶ Gokshura ▶ Goksura ▶ Ji li ▶ Puncturevine ▶ Puncturevine caltrop ▶ Tribulus 	<i>Tribulus terrestris</i>	<ul style="list-style-type: none"> ▶ Fruit ▶ Root 	Dried

References: Proper name: USDA 2018, PPRC 2010, API 2001, McGuffin et al. 2000; Common names: USDA 2018, PPRC 2010, Bensky et al. 2004, Chen and Chen 2004, API 2001, McGuffin et al. 2000; Source materials: PPRC 2010, Bensky et al. 2004, Chen and Chen 2004, API 2001, McGuffin et al. 2000, Kapoor 2001.

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.

The acceptable dosage forms for the age category listed in this monograph and specified route of administration are indicated in the Compendium of Monographs Guidance Document.

Use(s) or Purpose(s)

- ▶ 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

Claims for traditional use must include the term “Herbal Medicine”, “Traditional Chinese Medicine” or “Ayurveda”.

Dose(s)

Subpopulation(s)

Adults 18 years and older

Quantity(ies)



Traditional Chinese Medicine

Method of preparation: Decoction

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

Traditional Ayurveda Medicine

Arsa (haemorrhoid)

Method of preparation: Decoction

20 - 30 grams of dried fruit, per day (API 2001)

Method of preparation: Powder

3 - 6 grams of dried fruit, per day (API 2001)

Mutralla (diuretic), Mutrakrcchra (painful urination) and Vrsya (aphrodisiac)

Method of preparation: Decoction

- ▶ 20 - 30 grams of dried fruit, per day (API 2001)
- ▶ 20 - 30 grams of dried root, per day (API 2001)

Method of preparation: Powder

3 - 6 grams of dried fruit, per day (API 2001)

Direction(s) for use

No statement required.

Duration(s) of use

Mutralla (diuretic)

For occasional use only (APhA 2002; CPhA 2002).

Risk information

Caution(s) and warning(s)



All products except Vrsya (aphrodisiac for men)

- ▶ Consult a health care practitioner/health care provider/health care professional/doctor/physician if symptoms persist or worsen.
- ▶ Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you are pregnant (Chen and Chen 2004).

Traditional Chinese Medicine

Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use in case of qi or blood deficiency (Bensky et al. 2004).

Contraindication(s)

Traditional Chinese Medicine

Do not use this product if you have hypotension or liver deficiency (Bensky et al. 2004; Chen and Chen 2004).

Known adverse reaction(s)

All Products

Stop use if hypersensitivity/allergy occurs (Bensky et al. 2004).

All products except Mutrala (diuretic)

Diuretic effect may occur.

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

No statement required.

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.

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