

# Tribulus - Tribulus terrestris

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TRIBULUS - TRIBULUS TERRESTRIS Help on accessing alternative formats, such as Portable Document Format ( PDF ), Microsoft Word and PowerPoint ( PPT ) files, can be obtained in the alternate format help section. (PDF Version - 75 KB) 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 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. Restrictions when this monograph is combined with other monographs (Class II and III applications): Tribulus cannot be combined with other monographed ingredients with estrogenic or anti-estrogenic effects as a Class II application (e.g., Soybean Extracts and Isolates, DIM, Red clover isoflavone extract, Indole-3-carbinol, Brassica oleracea varieties (cruciferous vegetables), Angelica sinensis ). These products may be submitted as a Class III application. 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) Tribulus terrestris Caltrop Cat's-head Common dubblettje Devil's-thorn Devil's-weed Goathead Gokshura Goksura Ji li Puncturevine Puncturevine caltrop Tribulus Tribulus terrestris Fruit Root Dry References: Proper name: USDA 2025; PPRC 2020; Gardner and McGuffin 2013; API 2001; Common names: USDA 2025; PPRC 2020; Gardner and McGuffin 2013; Bensky et al. 2004; Chen and Chen 2004; API 2001; Source information: PPRC 2020; Gardner and McGuffin 2013; Bensky et al. 2004; Chen and Chen 2004; API 2001; 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. Acceptable dosage forms for any age category listed in this monograph for the specified route of administration are listed 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 2020). 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 or insufficient lactation, from constrained Liver qi (Bensky et al. 2004). Used in Traditional Chinese Medicine (TCM) to pacify the Liver, invigorate blood and dispel wind, improve vision, and relieve itching (PPRC 2020). Notes The above uses can be combined on the product label if from the same traditional or non-traditional system of medicine (e.g., Traditionally used in Ayurveda to help relieve Arsa and Mutrakrcchra). 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., Tribulus is traditionally used in Ayurveda as Mutrala). 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: Decoction, Decoction concentrate 6 - 10 grams of dried fruit, per day (PPRC 2020; Bensky et al. 2004; Chen and Chen 2004) Traditional Ayurveda Medicine Arsa (haemorrhoid) Methods of preparation: Decoction, Decoction concentrate 20 - 30 grams of dried fruit, per day (API 2001) Methods of preparation: Dry, Powdered,

Non-Standardized Ethanolic Extracts (Dry extract, Tincture, Fluid extract) 3 - 6 grams of dried fruit, per day (API 2001) Mutrala (diuretic), Mutrakrcchra (painful urination) and Vrsya (aphrodisiac) Methods of preparation: Decoction, Decoction concentrate 20 - 30 grams of dried fruit, per day (API 2001) 20 - 30 grams of dried root, per day (API 2001) Methods of preparation: Dry, Powdered, Non-Standardized Ethanolic Extracts (Dry extract, Tincture, Fluid extract) 3 - 6 grams of dried fruit, per day (API 2001) Direction(s) for use No statement required. Duration(s) of Use Mutrala (diuretic) For occasional use only (APhA 2002; CPhA 2002). Risk Information Caution(s) and warning(s) All products except Vrsya (aphrodisiac for men) Ask a health care practitioner/health care provider/health care professional/doctor/physician if symptoms persist or worsen. Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are pregnant (Chen and Chen 2004). Traditional Chinese Medicine Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you have qi or blood deficiency (Bensky et al. 2004). Contraindication(s) Traditional Chinese Medicine Do not use if you have low blood pressure 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) When using this product 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 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. References Cited APhA 2002: Berardi RR, DeSimone EM, Newton GD, Oszko MA, Popovich NG, Rollins CJ, Shimp LA, Tietze KJ, editors. Handbook of Nonprescription Drugs: An Interactive Approach to Self-Care. 13th edition. Washington (DC): American Pharmaceutical Association; 2002. API 2001: The Ayurvedic Pharmacopoeia of India. 1st edition, Part I, Volume I. Delhi (IN): The Controller of Publications; 2001 [Reprint of 1990 publication]. Bensky D, Clavey S, Toger E, Gamble A, editors. Chinese Herbal Medicine Materia Medica. 3rd edition. 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Delhi (IN): Chaukhamba Sanskrit Pratishthan; 2005 [Reprint of 2001]. PPRC 2020: Pharmacopoeia of the People's Republic of China. English Version. Volume I. Beijing (CN): Chinese Pharmacopoeia Commission; 2020. Premila MS. Ayurvedic Herbs: A Clinical Guide to the Healing Plants of Traditional Indian Medicine. New York (NY): Haworth Press Inc.; 2006. USDA 2025: United States Department of Agriculture, Agricultural Research Service (USDA ARS), Germplasm Resources Information Network (GRIN) - Global. U.S. National Plant Germplasm System; 2025. [Accessed 2025 January 21]. Available from: <https://npgsweb.ars-grin.gov/gringlobal/taxon/taxonomysearch> References Reviewed Adimoelja A, Adaikan PG. Protodioscin from herbal plant Tribulus terrestris L improves the male sexual functions, probably via DHEA. 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The effects of Tribulus terrestris on body composition and exercise performance in resistance-trained males. International Journal of Sport Nutrition and Exercise Metabolism 2000;10(2):208-215. Arsyad KM. Effect of protodioscin on the quantity and quality of sperms from males with moderate idiopathic oligozoospermia. Medika 1996;22(8):614-618. Brinker F. Herbal Contraindications and Drug Interactions: Plus Herbal Adjuncts With Medicines, expanded 4th edition. Sandy (OR): Eclectic Medical Publications; 2010. Brown GA, Vukovich MD, Martini ER, Kohut ML, Franke WD, Jackson DA, King DS. Endocrine and lipid responses to chronic androstenediol-herbal supplementation in 30 to 58 year old men. Journal of American College of Nutrition 2001a;20(5):520-528. Brown GA, Vukovich MD, Martini ER, Kohut ML, Franke WD, Jackson DA, King

DS. Effects of androstenedione-herbal supplementation on serum sex hormone concentrations in 30- to 59-year-old men. *International Journal for Vitamin and Nutrition Research* 2001b;71(5):293-301. Chandler F, editor. *Herbs: Everyday Reference for Health Professionals*. Ottawa (ON): Canadian Pharmacists Association and the Canadian Medical Association; 2000. Dinchev D, Janda B, Evstatieva L, Oleszek W, Aslani MR, Kostova I. Distribution of steroidal saponins in *Tribulus terrestris* from different geographical regions. *Phytochemistry* 2008;69(1):176-186. Ganzera M, Bedir E, Khan IA. Determination of steroidal saponins in *Tribulus terrestris* by reversed-phase high-performance liquid chromatography and evaporative light scattering detection. *Journal of Pharmaceutical Sciences* 2001;90(11):1752-1758. Gauthaman K, Adaikan PG, Prasad RN. Aphrodisiac properties of *Tribulus Terrestris* extract (Protodioscin) in normal and castrated rats. *Life Sciences* 2002;71(12):1385-1396. Gauthaman K, Ganesan AP. The hormonal effects of *Tribulus terrestris* and its role in the management of male erectile dysfunction - an evaluation using primates, rabbit and rat. *Phytomedicine* 2008;15(1-2):44-54. Jain SK, DeFilipps RA. *Medicinal Plants of India*. Michigan: Reference Publishers Inc; 1991. Jameel JK, Kneeshaw PJ, Rao VS, Drew PJ. Gynaecomastia and the plant product "*Tribulis terrestris*". *Breast* 2004;13(5): 428-430. Kohut ML, Thompson JR, Campbell J, Brown GA, Vukovich MD, Jackson DA, King DS. Ingestion of a dietary supplement containing dehydroepiandrosterone (DHEA) and androstenedione has minimal effect on immune function in middle-aged men. *Journal of American College of Nutrition* 2003;22(5):363-371. Kostova I, Dinchev D. Sappnins in *Tribulus terrestris* - chemistry and bioactivity. *Phytochemistry Reviews* 2005;4(2-3):111-137. Milanov S, Maleeva E, Taskov M. Tribestan effect on the concentration of some hormones in the serum of healthy volunteers. *Medico biologic information* 1985;4:27-29. Mills S, Bone K. *Principles and Practice of Phytotherapy*. Toronto (ON): Churchill Livingstone; 2000. Mills S, Bone K. *The Essential Guide to Herbal Safety*. St. Louis (MO): Elsevier Churchill Livingstone; 2005. Obreshkova D, Pangarova T, Milkov S, Dinchev D. Comparative analytical investigation of *Tribulus terrestris* preparations. *Pharmacia* 1998;15(2):11. Poprzecki S, Zebrowska A, Cholewa J. Ergogenic effects of *Tribulus terrestris* supplementation in men. *Journal of Human Kinetics* 2005;13:41-50. Premila MS. *Ayurvedic Herbs: A Clinical Guide to the Healing Plants of Traditional Indian Medicine*. Binghamton (NY): The Haworth Press inc; 2006. Rogerson S, Riches CJ, Jennings C, Weatherby RP, Meir RA, Marshall-Gradisnik SM. The effect of five weeks of *Tribulus terrestris* supplementation on muscle strength and body composition during preseason training in elite rugby league players. *Journal of Strength and Conditioning Research* 2007;21(2):348-353. Sengupta G, Hazra A, Kundu A, Ghosh A. Comparison of *Murraya koenigii* and *Tribulus terrestris*-based formulation versus tamsulosin in the treatment of benign prostatic hyperplasia in men aged > 50 years: a double-blind, double-dummy, randomized controlled trial. *Clinical Therapeutics* 2011;33(12):1943-1952. Setiawan L. *Tribulus terrestris* L. extract improves spermatozoa motility and increases the efficiency of acrosome reaction in subjects diagnosed with oligoastheno-teratozoospermia. *Journal of Panca Sarjana*. University of Airlangga 1996;5(2-3):35-40. Talasaz AH, Abbasi MR, Abkhiz S, Dashti-Khavidaki S. *Tribulus terrestris*-induced severe nephrotoxicity in a young healthy male. *Nephrology, Dialysis, Transplantation* 2010;25(11):3792-3973. Talbott SM, Hughes K. *The Health Professional's Guide to Dietary Supplements*. Baltimore (MD): Lippincott Williams & Wilkins; 2007. Williamson EM, editor. *Major Herbs of Ayurveda*. New York (NY): Churchill Livingstone; 2002. Report a problem on this page Date modified: 2019-03-01

## DOSAGE FORM(S)

Acceptable dosage forms for any age category listed in this monograph for the specified route of administration are listed in the Compendium of Monographs Guidance Document.

## RISK INFORMATION

Caution(s) and warning(s) All products except Vrsya (aphrodisiac for men) Ask a health care practitioner/health care provider/health care professional/doctor/physician if symptoms persist or worsen. Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are pregnant (Chen and Chen 2004). Traditional Chinese Medicine Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you have qi or blood deficiency (Bensky et al. 2004). Contraindication(s) Traditional Chinese Medicine Do not use if you have low blood pressure 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)

## 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.

## STORAGE CONDITION(S)

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:

## REFERENCES

Route of Administration Oral

Proper name(s)	Common name(s)	Source information		
Source material(s)	Part(s)	Preparation(s)		
Tribulus terrestris	CaltropCat's-headCommon dubbletjieDevil's-trainDevil's-wortGoatheadGokshuraGokshura Ji liPDmgurevineP	Tribulus terrestris		