

NATURAL HEALTH PRODUCT

KUTKI – *PICRORHIZA KURROOA*

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 20 , 2015

Proper name(s)

Picrorhiza kurrooa Royle ex Benth. (Plantaginaceae) (USDA 2003)

Common name(s)

- ▶ Kutki (API 2001)
- ▶ Picrorhiza (USDA 2003)

Source material(s)

- ▶ Root (WHO 2009; Duke *et al.* 2002; Williamson 2002)
- ▶ Rhizome (WHO 2009; Duke *et al.* 2002; Williamson 2002)

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 Ayurvedic Medicine as a bitter tonic to help stimulate appetite and aid digestion (stomachic) (Williamson 2002; API 2001; Kapoor 2001).
- ▶ Traditionally used in Ayurvedic Medicine as a hepatoprotectant/liver protectant (Williamson 2002; Kapoor 2001).
- ▶ Traditionally used in Ayurvedic Medicine as a laxative for the relief of occasional constipation (Sudarshan 2005; API 2001; Kapoor 2001).

Dose(s) Statement(s) to the effect of

Subpopulation(s)

Adults (≥ 18 years)

Quantity(ies)

Dry; Powder; Fluid extract; Tincture

Bitter tonic; Liver protectant

1-3 g dried rhizome/root, per day (WHO 2009; API 2001)

Laxative

1.5-3 g dried rhizome/root, per day (Paranjape 2005)

Directions for use

No statement required.

Duration of use Statement(s) to the effect of

Laxative

- ▶ For occasional use only.
- ▶ For use beyond 7 days, consult a health care practitioner (Pray 2006; CPhA 2002; HC 1994).

Risk information Statement(s) to the effect of

Caution(s) and warning(s)

All products

If you have or develop abdominal pain, nausea, fever, vomiting or diarrhea consult a health care practitioner (Williamson 2002; Kapoor 2001).

Laxative

If symptoms persist or worsen, consult a health care practitioner

Contraindication(s)

All products

If you are pregnant or breastfeeding, do not use this product (Brinker 2010).

Known adverse reaction(s)

Bitter tonic; Liver protectant

Laxative effect may occur (Sudarshan 2005; API 2001; Kapoor 2001).

Non-medicinal ingredients

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.
- ▶ *Picrorhiza kurrooa* is listed in Appendix II of the Convention on International Trade of Endangered Species of Wild Fauna and Flora (CITES). This species is protected under Canada's Wild Animal and Plant Protection and Regulation of International and Interprovincial Trade Act (WAPPRIITA) and its Regulations (GC 2013). Please ensure the required CITES import/export permit accompanies each shipment. For more information, see http://www.cites.ec.gc.ca/eng/sct3/sct3_4_e.cfm (EC 2012).

References cited

API 2001: The Ayurvedic Pharmacopoeia of India. Part I, Volume II, First Edition. Delhi (IN): The Controller of Publications; 1991. [Accessed 2012 September 24]. Available from: <http://www.ccras.nic.in/>



- Brinker F. Herbal Contraindications and Drug Interactions: Plus Herbal Adjuncts with Medicines, expanded 4th edition. Sandy (OR): Eclectic Medical Publications; 2010.
- CPhA 2002: Repchinsky C, editor-in-chief. Patient Self-Care: Helping Patients Make Therapeutic Choices. 1st edition. Ottawa (ON): Canadian Pharmacists Association; 2002.
- Duke JA, Bogenschutz-Godwin MJ, duCellier J, Duke PK. Handbook of Medicinal Herbs. 2nd edition. Boca Raton (FL): CRC Press; 2002.
- EC 2012: Environment Canada. Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES), Schedule II. *Picrorhiza kurrooa* [Internet]. Ottawa (ON): Canadian Wildlife Service, Environment Canada. [Accessed 2014 July 4]. Available from: <http://ec.gc.ca/cites/default.asp?lang=En&n=3E097D04-1>.
- GC 2013. Wild Animal and Plant Protection and Regulation of International and Interprovincial Trade Act. [Act current to 2014 May 12; last amended on 2010 December 10; Accessed 2014-07-02]. Available from: <http://laws-lois.justice.gc.ca/eng/acts/W-8.5/index.html>
- HC 1994: Laxatives: General - Laxatives - Labelling Standard [Internet]. Ottawa (ON): Drugs and Health Products; Health Canada; 1994. [Accessed 2012 June 5]. Available from: <http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/label-etiquet-pharm/laxat-eng.php>
- Kapoor LD. Handbook of Ayurvedic Medicinal Plants. Baton Roca (FL): CRC Press LLC; 2001.
- Paranjpe P. Indian Medicinal Plants: Forgotten Healers: A Guide to Ayurvedic Herbal Medicine. Delhi (IN): Chaukhamba Sanskrit Pratishthan; 2005.
- Pray WS. Non-Prescription Product Therapeutics, 2nd edition. New York (NY): Lippincott Williams & Wilkins; 2006.
- Sudarshan SR. Encyclopaedia of Indian Medicine, Materia Medica—Herbal Drugs. Volume 4. Bangalore (IN): Popular Prakashan; 2005.
- USDA 2003: United States Department of Agriculture, Agricultural Research Service, National Genetic Resources Program. Germplasm Resources Information Network (GRIN). [Internet]. National Germplasm Resources Laboratory, Beltsville (MD). [*Picrorhiza kurrooa* Royle ex Benth. Last updated 2003 March 05; Accessed 2014 June 03]. Available from: http://www.ars-grin.gov/cgi-bin/npgs/html/tax_search.pl
- WHO 2009: World Health Organization. WHO Monographs on Selected Medicinal Plants, Volume 4. Geneva (CH): World Health Organization; 2009.
- Williamson EM, editor. Major Herbs of Ayurveda. Edinburgh (GB): Churchill Livingstone; 2002.

References reviewed

Ansari RA, Tripathi SC, Patnaik GK, Dhawan BN. Antihepatotoxic properties of picroliv: an active fraction from rhizomes of *Picrorhiza kurroa*. *Journal of Ethnopharmacology* 1991;34: 61-68.

CITES . Convention on International Trade in Endangered Species of Wild Fauna and Flora. March 3, 1973. [Accessed 2014-06-27]. Available from: <http://www.cites.org/>

Lupper S. A Review of Plants Used in the Treatment of Liver Disease: Part 1. *Alternative Medicine Review* 1999;3(6):410-421.

MHFW 2007: Ministry of Health and Family Welfare, Monograph on Popular and Effective Select Traditional Home Remedies. [Internet]. Department of Ayush, New Delhi, In collaboration with WHO Country office for India. 2006-2007:30. [Consulted: 2014 June 11]. Available from: <http://fr.scribd.com/doc/162277056/Traditional-Medicine-Monograph-on-Popular-Home-Remedies>

Nadkarni AK. Dr. KM Nadkarni's Indian Materia Medica, With Ayurvedic, Unani-Tibbi, Siddha, Allopathic, Homeopathic, Naturopathic & Home Remedies, Appendices & Indexes, Volume One. Bombay Popular Prakashan;1976.

Saraswat B, Visen PKS, Parnaik GK, Dhawan BN. *Ex vivo* and *in vivo* investigations of picroliv from *Picrorhiza kurroa* in an alcohol intoxication model in rats. *Journal of Ethnopharmacology* 1999;66:263-269.

Shetty SN, Mengi S, Vaidya R, Vaidya ADB. A study of standardized extracts of *Picrorhiza kurroa* Royle ex Benth in experimental nonalcoholic fatty liver disease. *Journal of Ayurveda Integrative Medicine* 2010;1(3):2013-2010.

Shukla B, Visen PKS, Patnaik GK, Dhawan BN. Choloretic Effect of Picroliv, the Hepatoprotective Principle of *Picrorhiza kurroa*. *Planta Medica* 1991;57:29-33.

Vaidya AB, Antarkar DS, Doshi JC, Bhatt AD, Ramesh VV, Vora PV, Perissond DD, Baxi AJ, Kale PM. *Picrorhiza kurroa* (Kutki) Boyle ex Benth as a hepatoprotective agent – experimental & clinical studies. *Journal of Postgraduate Medicine* 1996;42(4):105-108.