

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

Date October 30, 2018

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>Picrorhiza kurrooa</i>	<ul style="list-style-type: none"> ▶ Kutki ▶ Picrorhiza 	<i>Picrorhiza kurrooa</i>	<ul style="list-style-type: none"> ▶ Root ▶ Rhizome 	Dried

References: Proper name: USDA 2018; Common names: USDA 2018, API 2001; Source materials: WHO 2009, Duke et al. 2002, Williamson 2002.

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

The following combined use(s) or purpose(s) is/are also acceptable:

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

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)

Methods of preparation: Dry, Powder, Non-Standardised Ethanolic Extracts (Dry extract, Tincture, Fluid extract)

Bitter tonic; Liver protectant

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

Laxative

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

Direction(s) for use

No statement required.



Duration(s) of use

Laxative

Consult a health care practitioner/health care provider/health care professional/doctor/physician for use beyond 7 days (Pray 2006; CPhA 2002; HC 1994).

Risk information

Caution(s) and warning(s)

All products

Consult a health care practitioner/health care provider/health care professional/doctor/physician if you have or develop abdominal pain, nausea, fever, vomiting or diarrhea (Williamson 2002; Kapoor 2001).

Bitter tonic; Laxative

Consult a health care practitioner/health care provider/health care professional/doctor/physician if symptoms persist or worsen.

Contraindication(s)

All products

Do not use this product if you are pregnant or breastfeeding (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).

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