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 (WAPPRITA) 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**


References reviewed


