NATURAL HEALTH PRODUCT

DEVIL’S CLAW – HARPAGOPHYTUM

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: August 16, 2017

Proper name(s):
- *Harpagophytum procumbens* (Burch.) DC. ex Meisn. (Pedaliaceae) (USDA 2017)
- *Harpagophytum zeyheri* Decne. (Pedaliaceae) (USDA 2017)

Common name(s):
Devil’s claw (McGuffin et al. 2000)

Source material(s):
Secondary root tubers (ESCOP 2003; Blumenthal et al. 2000; Bradley 1992)

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):

- (Traditionally used) in Herbal Medicine as a bitter to help stimulate appetite (EMA 2016; ESCOP 2003; Blumenthal et al. 2000; Bradley 1992).
- (Traditionally) used in Herbal Medicine to help relieve digestive disturbances such as dyspepsia (EMA 2016; ESCOP 2003; Blumenthal et al. 2000; Bradley 1992).
- Used in Herbal Medicine to help relieve joint pain associated with osteoarthritis (EMA 2016; Mills and Bone 2005; ESCOP 2003; Hoffmann 2003).

Dose(s):

Subpopulation(s):

Adults (≥ 18 years)

Quantity(ies):

**Preparation:** Dry, powder, dry extract, liquid extract, fluid extract, tincture, decoction, infusion

*For stimulation of appetite:*

0.6 - 1.5 g dried secondary root tubers, per day (EMA 2016; Blumenthal et al. 2000; Bradley 1992)

*For relief of digestive disturbances:*

0.6 - 4.5 g dried secondary root tubers, per day (EMA 2016; Blumenthal et al. 2000; Bradley 1992)

*For the relief of joint pain associated with osteoarthritis:*

0.6 - 7.5 g dried secondary root tubers, per day (EMA 2016; Mills and Bone 2005; ESCOP 2003; Hoffmann 2003; Bradley 1992)

See Appendix 1 for examples of appropriate dosage preparations, frequencies of use, and directions for use according to cited references. The purpose of Appendix 1 is to provide guidance to industry.

Duration of use:

*For the relief of joint pain associated with osteoarthritis:*

Use for a minimum of 2-3 months to see beneficial effects (ESCOP 2003).
Risk information:

Caution(s) and warning(s):
▶ If symptoms persist or worsen, consult a health care practitioner.
▶ If you are pregnant or breastfeeding, consult a health care practitioner prior to use.

Contraindication(s):

No statement required.

Known adverse reaction(s):

No statement required.

Non-medicinal ingredients:

Must be chosen from the current Natural Health Products Ingredients Database (NHPID) and must meet the limitations outlined in the database.

Specifications:

▶ The finished product specifications must be established in accordance with the requirements described in the Natural and Non-Prescription Health Products Directorate (NNHPD)’s Quality of Natural Health Products Guide.
▶ The medicinal ingredient must comply with the requirements outlined in the NHPID.

References cited:


References reviewed:


Appendix 1: Examples of appropriate dosage preparations, frequencies of use and directions for use

For stimulation of appetite:

Dried secondary root tuber:
\[ 1.5 \text{ g, per day (Blumenthal et al. 2000)} \]

Decoction: \[ 0.5 \text{ g dried secondary root tubers, 3 times per day (Blumenthal et al. 2000; Bradley 1992)} \]

**Directions for use:** Place dried secondary root tubers in 150 ml of water, bring to a boil, and simmer (Blumenthal et al. 2000).

Fluidextract: \[ 0.5 \text{ g dried equivalent, 3 times per day (1:1, 0.5 ml) (Blumenthal et al. 2000)} \]

Tincture: \[ 0.2 \text{ g dried equivalent, 3 times per day (1:5, 25\% alcohol, 1 ml) (Bradley 1992)} \]

For relief of digestive disturbances:

Dried secondary root tuber:
\[ 4.5 \text{ g, per day (Blumenthal et al. 2000)} \]

Infusion: \[ 1.5 \text{ g dried secondary root tubers, 3 times per day (Blumenthal et al. 2000)} \]

**Directions for use:** Pour 300 ml of boiling water over 4.5 g dried secondary root tubers and steep for 8 hours. Drink 100 ml, 3 times per day (Blumenthal et al. 2000).

Decoction:

\[ 1.5 \text{ g dried secondary root tubers, 3 times per day (Blumenthal et al. 2000)} \]
\[ 0.5 \text{ g dried secondary root tubers, 3 times per day (Bradley 1992)} \]

**Directions for use:** Place dried secondary root tubers in 150 ml of water, bring to a boil, and simmer (Blumenthal et al. 2000).

Fluidextract: \[ 1.5 \text{ g dried equivalent, 3 times per day (1:1, 1.5 ml) (Blumenthal et al. 2000)} \]

Tincture: \[ 0.2 \text{ g dried equivalent, 3 times per day (1:5, 25\% alcohol, 1 ml) (Bradley 1992)} \]
For the relief of joint pain associated with osteoarthritis:

Dried secondary root tuber:
- 1.5-6 g, per day (Mills and Bone 2005)
- 2-5 g, per day (ESCOP 2003)
- 4.5 g, per day (Blumenthal et al. 2000)

Infusion: 1.5 g dried secondary root tubers, 3 times per day (Blumenthal et al. 2000)

**Directions for use:** Pour 300 ml of boiling water on 4.5 g dried secondary root tubers and steep for 8 hours. Drink 100 ml, 3 times per day (Blumenthal et al. 2000).

Decoction:
- 1.5-6 g dried secondary root tubers, per day (Mills and Bone 2005)
- 1.5 g dried secondary root tubers, 3 times per day (Blumenthal et al. 2000)
- 1.5-2.5 g dried secondary root tubers, 3 times per day (Bradley 1992)

**Directions for use:** Place dried secondary root tubers in 150 ml of water, bring to a boil, and simmer (Blumenthal et al. 2000).

Fluidextract:
- 1.5 g dried equivalent, 3 times per day (1:1, 1.5 ml) (Blumenthal et al. 2000)
- 1-2 g dried equivalent, 3 times per day (1:1, 25% ethanol, 1-2 ml) (Bradley 1992)

Tincture: 0.2-0.4 g dried equivalent, 3 times per day (1:5, 40% alcohol, 1-2 ml) (Hoffmann 2003)