



NATURAL HEALTH PRODUCT

DANDELION - *TARAXACUM OFFICINALE*

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

May 21, 2013

Proper name(s)

Taraxacum officinale F.H. Wigg. (Asteraceae) (USDA 2012; McGuffin et al. 2000)

Common name(s)

- ▶ Dandelion (USDA 2012; McGuffin et al. 2000; Wiersema and León 1999)
- ▶ Lion's tooth (USDA 2012; McGuffin et al. 2000; Wiersema and León 1999)

Source material(s)

- ▶ Leaf¹ (BHP 1996)
- ▶ Root² (BHP 1996)
- ▶ Whole plant³ (Blumenthal et al. 1998; BHC 1996)

Notes

1. Collected before flowering (BHC 1996)
2. Collected in the autumn (BHC 1996)
3. Collected while flowering (Blumenthal et al. 1998; BHC 1996)

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

LEAF

- ▶ Traditionally used in Herbal Medicine to increase the amount of urine to achieve flushing of the urinary tract as an adjuvant in minor urinary complaints (EMA 2009).
- ▶ (Traditionally) used in Herbal Medicine as a diuretic (Mills and Bone 2005; Hoffmann 2003; BHC 1992; BHP 1983).
- ▶ (Traditionally) used in Herbal Medicine as a laxative (aperient) (Mills and Bone 2005; Hoffmann 2003; BHP 1983).
- ▶ (Traditionally) used in Herbal Medicine to help increase bile flow (choleric) (Godfrey et al. 2010; Mills and Bone 2005; Hoffmann 2003; BHC 1992; BHP 1983).
- ▶ (Traditionally) used in Herbal Medicine to help treat digestive disturbances (dyspepsia) (Godfrey et al. 2010; Mills and Bone 2005; BHC 1992; Grieve 1971 [1931]).

ROOT

- ▶ (Traditionally) used in Herbal Medicine as an alterative to help relieve dermatological conditions (Blumenthal et al. 2000; Ellingwood 1983 [1919]; Felter and Lloyd 1983 [1898]), such as eczema (Wichtl 2004).
- ▶ (Traditionally) used in Herbal Medicine as a diuretic (Mills and Bone 2005; Hoffmann 2003; Ellingwood 1983 [1919]; BHP 1983; Wren 1907).
- ▶ (Traditionally) used in Herbal Medicine as a laxative (aperient) (Godfrey et al. 2010; Mills and Bone 2005; Hoffmann 2003; BHC 1996; BHP 1983).
- ▶ (Traditionally) used in Herbal Medicine to help increase bile flow (cholagogue and choleric) (Hoffmann 2003; BHC 1992; BHP 1983; Ellingwood 1983 [1919]).
- ▶ (Traditionally) used in Herbal Medicine to help stimulate appetite (Godfrey et al. 2010; EMA 2009ESCOP 2003; BHC 1992; Grieve 1971 [1931]).
- ▶ (Traditionally) used in Herbal Medicine to help treat digestive disturbances (dyspepsia) (Godfrey et al. 2010; Mills and Bone 2005; BHC 1992; Grieve 1971 [1931]).

WHOLE PLANT

- ▶ Used in Herbal Medicine as a diuretic (WHO 2007; Wichtl 2004; Blumenthal et al. 1998; BHC 1992).
- ▶ Used in Herbal Medicine to help increase bile flow (cholagogue and choleric) (WHO 2007; Wichtl 2004; Blumenthal et al. 1998; BHC 1992).



- ▶ (Traditionally) used in Herbal Medicine to help stimulate appetite (EMA 2009; WHO 2007; Witchl 2004; Blumenthal et al. 1998; BHC 1992).
- ▶ (Traditionally) used in Herbal Medicine to help treat digestive disturbances (dyspepsia) (EMA 2009; WHO 2007; Witchl 2004; Blumenthal et al. 1998; BHC 1992).
- ▶ Traditionally used in Herbal Medicine to increase the amount of urine to achieve flushing of the urinary tract as an adjuvant in minor urinary complaints (EMA 2009).

Dose(s)

Statement(s) to the effect of

Subpopulation(s)

- ▶ Adults (≥ 18 years)
- ▶ Adolescents (12-17 years)

Quantity(ies)

LEAF

Preparations equivalent to 1.2-30 g dried leaf, per day (Mills and Bone 2005; Hoffmann 2003; Blumenthal et al. 2000, 1998; BHC 1992; BHP 1983)

ROOT

Preparations equivalent to 1.5-24 g dried root, per day (Mills and Bone 2005; Hoffmann 2003; BHC 1992; BHP 1983)

WHOLE PLANT

Preparations equivalent to 3-30 g dried whole plant, per day (EMA 2009; WHO 2007; Witchl 2004; Blumenthal et al. 2000, 1998).

Directions for use

Flushing of urinary tract

To ensure an increase of the amount of urine, adequate fluid intake is required during treatment (EMA 2009).

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

Duration of use

Diuretic



For occasional use only (APhA 2002; CPhA 2002).

Flushing of urinary tract, indigestion, or loss of appetite

If symptoms persist beyond 2 weeks, consult a health care practitioner (EMA 2009).

Risk information Statement(s) to the effect of

Caution(s) and warning(s)

All products

If you have liver or gall bladder diseases, and/or intestinal obstruction, consult a health care practitioner prior to use (Godfrey et al. 2012; ESCOP 2003; Brinker 2001; BHC 1992).

Constipation, urinary retention, indigestion, or loss of appetite

If symptoms persist or worsen, consult a health care practitioner.

Contraindication(s)

Preparations equivalent to ≥ 10 g per day dried leaf and/or dried root

If you have heart disease, high or low blood pressure, kidney or liver disorder, diabetes or edema (swelling of hands, face and feet) or are taking products containing diuretics, do not use this product (Goksu et al. 2010; EMA 2009; Hunt et al. 2005; Green et al. 2002; Mujais and Katz 2000; Carlsen et al. 1990; Kuller et al. 1986; Artz et al. 1966).

Known adverse reaction(s)

No statement required.



Non-medicinal ingredients

Must be chosen from the current NHPD *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 NHPD *Quality of Natural Health Products Guide*.
- ▶ The medicinal ingredient must comply with the requirements outlined in the *Natural Health Products Ingredients Database* (NHPID). In addition, the medicinal ingredient may comply with the specifications outlined in the DANDELION HERB WITH ROOT or the DANDELION ROOT monograph published in the European Pharmacopoeia (Ph.Eur. 2013).

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Appendix 1 Examples of appropriate dosage preparations and frequencies of use

LEAF

Dried leaf

- ▶ 12-30 g, per day (Mills and Bone 2005)
- ▶ 4-10 g, thrice daily/three times daily (Blumenthal et al. 1998; BHC 1992; BHP 1983)

Infusion

- ▶ 12-30 g dried leaf, per day (Mills and Bone 2005)
- ▶ 4-10 g dried leaf, thrice daily/three times daily (BHC 1992; BHP 1983)

Fluidextract

- ▶ [6-11.5 g dried equivalent, per day]
6-11.5 ml (1:1) (Mills and Bone 2005)
- ▶ [4-10 g dried equivalent, 3 times per day]
4-10 ml, three times daily (1:1, 25% ethanol) (Blumenthal et al. 2000)
- ▶ [4-10 g dried equivalent, 3 times per day]
4-10 ml, thrice daily (1:1, 25% alcohol) (BHP 1983)

Tincture

- ▶ [1.2-3 g dried equivalent, per day]
6-15 ml (1:5) (Mills and Bone 2005)
- ▶ [1-2 g dried equivalent, 3 times per day]
5-10 ml (1:5, 40% alcohol) (Hoffmann 2003)
- ▶ [0.4-1 g dried equivalent, 3 times per day]
2-5 ml, three times daily (1:5, 25% ethanol) (BHC 1992)

ROOT

Dried root

- ▶ 6-24 g, per day (Mills and Bone 2005)
- ▶ 3-5 g, 3 times per day (BHC 1992)
- ▶ 2-8 g, thrice daily (BHP 1983)

Infusion or decoction

- ▶ 6-24 g dried root, per day (Mills and Bone 2005)
- ▶ 3-5 g dried root, 3 times per day (BHC 1992)
- ▶ 2-8 g, thrice daily (BHP 1983)



Fluidextract

[2-8 g dried equivalent, 3 times per day]
2-8 ml, thrice daily (1:1, 30% alcohol) (BHP 1983)

Tincture

- ▶ [1.5-3 g dried equivalent, per day]
(1:2, 3-6 ml) (Mills and Bone 2005)
- ▶ [3-6 g dried equivalent, per day]
(1:5, 15-30 ml) (Mills and Bone 2005)
- ▶ [0.5-1 g dried equivalent, 3 times per day]
(1:5, 60% alcohol, 2.5-5 ml) (Hoffmann 2003)
- ▶ [1-2 g dried equivalent, 3 times per day]
5-10 ml, three times daily (1:5, 25% ethanol) (BHC 1992)
- ▶ [1-2 g dried equivalent, 3 times per day]
5-10 ml, three times per day (1:5, 45% alcohol) (BHP 1983)

ROOT AND AERIAL PART (Blumenthal et al. 2000)

Unless otherwise prescribed

3-4 g of cut or powdered root and herb three times daily.

Decoction

Boil 3-4 g cut or powdered root and herb in 150 ml water.

(Ed. Note: The decoction instructions in the German Standard License monograph are as follows: Boil 1-2 teaspoonfuls (2.4-4.4 g) and strain after 15 minutes, twice daily in the morning and evening.)

Infusion

Steep 1 tablespoon cut root and herb in 150 ml water.

Dry native extract

4:1 (w/w): 0.75-1 g.

Fluidextract

1:1 (g/ml): 3-4 ml.

Tincture

10-15 drops, three times daily.



(Ed. Note: The Commission E-recommended tincture dosage of 10-15 drops, three times daily, does not correlate closely with the Commission E daily dosage of 3-4 g dried root and herb. No justification can be found in the literature for such a low tincture dosage, in drops as opposed to milliliters. Most herbal references recommend 5-10 ml, three times daily, which relates to the Commission E daily dosage of 3-4 g dried root.)