



NATURAL HEALTH PRODUCT

DANDELION (*TARAXACUM OFFICINALE*) JUICE

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 juice (Blumenthal et al. 2000; BHC 1992; BHP 1983)

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 alternative 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).

Dose(s)

Statement(s) to the effect of

Subpopulation(s)

- ▶ Adults (≥ 19 years)
- ▶ Adolescents (12-18 years)

Quantity(ies)

LEAF

Juice of fresh leaf: 5-10 ml, 2 times per day (EMA 2009; BHC 1992).

ROOT

Juice of fresh root: 4-8 ml, 3 times per day (BHC 1992; BHP 1983).

WHOLE PLANT

Juice of fresh whole plant: 5-10 ml, 3 times per day (EMA 2009; Blumenthal et al. al. 2000).

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 the 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. 2010; EMA 2009; 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 plant material

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 (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

Juice of fresh leaf

5-10 ml, twice daily (BHC 1992)

ROOT

Expressed juice from fresh root

4-8 ml, three times per day (BHC 1992)

Juice of fresh root

4-8 ml, thrice daily (BHP 1983)

ROOT AND AERIAL PARTS (Blumenthal et al. 2000)

Succus

5-10 ml pressed sap from fresh plant.