



NATURAL HEALTH PRODUCT

DANDELION 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 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>Taraxacum officinale</i>	Dandelion juice	<i>Taraxacum officinale</i>	<ul style="list-style-type: none"> ▶ Leaf ▶ Root ▶ Whole plant 	Juice

References: Proper name: USDA 2018, McGuffin et al. 2000; Common name: Blumenthal et al. 2000, BHC 1992, BHP 1983; Source materials: Blumenthal et al. 1998, BHC 1992.

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)

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 upset (dyspepsia) (Godfrey et al. 2010; Mills and Bone 2005; BHC 1992; Grieve 1971).

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

- ▶ (Traditionally) used in Herbal Medicine to help increase bile flow (choleric) and treat digestive upset (dyspepsia) (Godfrey et al. 2010; Mills and Bone 2005; Hoffmann 2003; BHC 1992; BHP 1983; Grieve 1971).

ROOT

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

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

- ▶ (Traditionally) used in Herbal Medicine as a diuretic and a laxative (aperient) (Godfrey et al. 2010; Mills and Bone 2005; Hoffmann 2003; BHC 1992; BHP 1983; Ellingwood 1983; Wren 1907).
- ▶ (Traditionally) used in Herbal Medicine to help increase bile flow (cholagogue and choleric), treat digestive upset (dyspepsia) and stimulate appetite (Godfrey et al. 2010; EMA 2009; ESCOP 2003; Hoffmann 2003; BHC 1992; BHP 1983; Ellingwood 1983; Grieve 1971).



WHOLE PLANT

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

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

- ▶ Used in Herbal Medicine as a diuretic to achieve flushing of the urinary tract as an adjuvant in minor urinary complaints (EMA 2009; WHO 2007; Wichtl 2004; Blumenthal et al. 1998; BHC 1992).
- ▶ Used in Herbal Medicine to help stimulate appetite, increase bile flow (cholagogue and cholaretic) and treat digestive upsets (dyspepsia) (EMA 2009; WHO 2007; Witchl 2004; Blumenthal et al. 1998; BHC 1992).

Note

Claims for traditional use must include the term “Herbal Medicine”, “Traditional Chinese Medicine”, or “Ayurveda”.

Dose(s)

Subpopulation(s)

Adolescents 12-17 years and Adults 18 years and older

Quantity(ies)

Method of preparation: Juice

LEAF

10-20 milliliters of juice of fresh leaf, per day; Not to exceed 10 milliliters per single dose (EMA 2009; BHC 1992).

ROOT

12-24 millilitres of juice of fresh root, per day; Not to exceed 8 milliliters per single dose (BHC 1992; BHP 1983).



WHOLE PLANT

15-30 milliliters of juice of fresh whole plant, per day; Not to exceed 10 milliliters per single dose (EMA 2009; Blumenthal et al. al. 2000).

Direction(s) for use

Flushing of urinary tract

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

Duration(s) of use

Diuretic

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

Flushing of the urinary tract, Indigestion, and Loss of appetite

Consult a health care practitioner/health care provider/health care professional/doctor/physician if symptoms persist beyond 2 weeks (EMA 2009).

Risk information

Caution(s) and warning(s)

All products

Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you have liver or gall bladder diseases, and/or intestinal obstruction (Brinker 2010; Godfrey et al. 2010; EMA 2009; ESCOP 2003; BHC 1992).

Constipation, Flushing of the urinary tract, Indigestion, and Loss of appetite

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

Contraindication(s)

Products providing 10 ml or more of juice, per day

Do not use this product 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 (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 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.

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