EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

Community herbal monograph on *Taraxacum officinale* Weber ex Wigg., folium

Final

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BG (bălgarski): CS (čeština): DA (dansk): DE (Deutsch): Löwenzahnblätter EL (elliniká): EN (English): dandelion leaf ES (espanol): Diente de león, hoja de ET (eesti keel): FI (suomi): FR (français): Pissenlit (feuille de) HU (magyar): IT (italiano):	LT (lietuvių kalba): LV (latviešu valoda): Pienenes lapas MT (malti): Werqa taċ-Ċikwejra Salvaġġa NL (nederlands): PL (polski): Liść minszka lekarskiego PT (português): RO (română): SK (slovenčina): SL (slovenščina): SV (svenska): *IS (íslenska)*: *NO (norsk)*: Løvetannblad

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Community herbal monograph on *Taraxacum officinale* Weber ex Wigg., folium

1. Name of the medicinal product

To be specified for the individual finished product.

2. Qualitative and quantitative composition[1]

Well-established use	Traditional use
	With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended *Taraxacum officinale* Weber ex Wigg., folium (dandelion leaf) i) Herbal substance Not applicable. ii) Herbal preparations a) Dried leaves, comminuted b) Liquid extract (DER 1:1), extraction solvent ethanol 25% (V/V) c) Expressed juice[2] from fresh leaves

3. Pharmaceutical form

Well-established use	Traditional use
	Herbal preparations in liquid dosage forms for oral use. Comminuted herbal substance as herbal tea for oral use. The pharmaceutical form should be described by the European Pharmacopoeia full standard term.

1 The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance.
2 The material complies, when dried, with Ph. Eur. monograph on herbal drugs.

4. Clinical particulars

4.1. Therapeutic indications

Well-established use	Traditional use
	Traditional herbal medicinal product to increase the amount of urine to achieve flushing of the urinary tract as an adjuvant in minor urinary complaints. The product is a traditional herbal medicinal product for use in the specified indication exclusively based upon long-standing use.

4.2. Posology and method of administration

Well-established use	Traditional use
	Posology *Adolescents, adults and elderly* a) Comminuted herbal substance: Single dose 4-10 g as an infusion, 3 times daily b) Liquid extract: Single dose 4-10 ml, 3 times daily c) Expressed juice from fresh leaves: Single dose 5-10 ml, 2 times daily The use in children under 12 years of age is not recommended (see section 4.4 'Special warnings and precautions for use'). **Duration of use** If the symptoms persist longer than 2 weeks during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted. **Method of administration** Oral use. To ensure an increase of the amount of urine, adequate fluid intake is required during treatment.

4.3. Contraindications

Well-established use	Traditional use
	Hypersensitivity to the active substance or to plants of the Asteraceae (Compositae) family. Obstructions of bile ducts, cholangitis, liver diseases, gallstones, active peptic ulcer and any other biliary diseases.

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	The use in patients with renal failure and/or diabetes, and/or heart failure should be avoided because of possible risks due to hyperkalemia. The use in children under 12 years of age has not been established due to lack of adequate data. If complaints or symptoms such as fever, dysuria, spasms or blood in urine occur during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted. For extracts containing ethanol, the appropriate labelling for ethanol, taken from the 'Guideline on excipients in the label and package leaflet of medicinal products for human use', must be included.

4.5. Interactions with other medicinal products and other forms of interaction

Well-established use	Traditional use
	None reported.

4.6. Pregnancy and lactation

Well-established use	Traditional use
	Safety during pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy and lactation is not recommended.

4.7. Effects on ability to drive and use machines

Well-established use	Traditional use
	No studies on the effect on the ability to drive and use machines have been performed.

4.8. Undesirable effects

Well-established use	Traditional use
	Allergic reactions may occur. The frequency is not known. If other adverse reactions not mentioned above occur, a doctor or a qualified health care practitioner should be consulted.

4.9. Overdose

Well-established use	Traditional use
	No case of overdose has been reported.

5. Pharmacological properties

5.1. Pharmacodynamic properties

Well-established use	Traditional use
	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.

5.2. Pharmacokinetic properties

Well-established use	Traditional use
	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.

5.3. Preclinical safety data

Well-established use	**Traditional use**
	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended, unless necessary for the safe use of the product. Adequate tests on genotoxicity have not been performed. Tests on reproductive toxicity and carcinogenicity have not been performed.

6. Pharmaceutical particulars

Well-established use	**Traditional use**
	Not applicable.

7. Date of compilation/last revision

12 November 2009