European Medicines Agency
Evaluation of Medicines for Human Use

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COMMITTEE ON HERBAL MEDICINAL PRODUCTS (HMPC)

DRAFT

COMMUNITY HERBAL MONOGRAPH ON *TARAXACUM OFFICINALE* WEBER ex WIGG., RADIX CUM HERBA

DISCUSSION IN WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (MLWP)	May 2008 September 2008 November 2008 January 2009
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ADOPTION BY HMPC	

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KEYWORDS	Herbal medicinal products; HMPC; Community herbal monographs; traditional use; *Taraxacum officinale* Weber ex Wigg.; Taraxaci radix cum herba; dandelion root with herb

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COMMUNITY HERBAL MONOGRAPH ON *TARAXACUM OFFICINALE* WEBER ex WIGG., RADIX CUM HERBA

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., radix cum herba (dandelion root with herb) i) Herbal substance Not applicable ii) Herbal preparations a) Dry extract (5.6-8.4:1), extraction solvent ethanol 60% (v/v) b) Liquid extract (1:0.9-1.1) extraction solvent ethanol 30% (v/v) c) Liquid extract (0.75:1) extraction solvent ethanol 30% (v/v) d) Expressed juice[2] from fresh flowering Taraxaci radix cum herba (1 : 0.6 - 0.8). e) Expressed juice[2] from fresh flowering Taraxaci radix cum herba (1.75:1) f) Dried root with herb, comminuted

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

3. PHARMACEUTICAL FORM

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

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Well-established use	Traditional use
	Indication a) Traditional herbal medicinal product used in mild dyspeptic/gastrointestinal disorders. Indication b) 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 specified indications exclusively based upon long-standing use.

4.2. Posology and method of administration

Well-established use	Traditional use
	Posology Indication a) *Adolescents over 12 years of age and adults* a) 2 times daily 1 coated tablet containing 300 mg dry extract or 3 times daily 1 - 2 coated tablets containing 150 mg dry extract each b) 3 times daily 90 drops liquid containing 100 % liquid extract, (90 drops = 3.15 ml = 3.31g) c) 3 times daily 35 drops liquid containing 0.266 g liquid extract, (35 drops = ca. 1 ml = 1g) d) 3 times daily 10 - 15 ml liquid containing 100 % expressed juice e) 3 times daily 10 - 15 ml liquid containing 100 % expressed juice f) Dried root with herb, comminuted:

	up to four times daily (750 mg to 4000 mg/daily) for tea preparation Indication b) *Adolescents over 12 years of age and adults* f) Dried root with herb, comminuted: up to four times daily (750 mg to 4000 mg/daily) The use is not recommended in children under 12 years of age (see also 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 the biliary or intestinal tract, acute gallbladder inflammation, or in case of active peptic ulcer.

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	For tinctures and 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. The use in adolescents over 12 years of age and adults all with renal failure and/or diabetes, and/or heart failure should be avoided because of possible complications due to hyperkalaemia.

	The use in children under 12 years of age is not recommended because of the lack of available experience. 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.

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, 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
	Epigastric pain and hyperacidity may occur. The frequency is not known. Allergic reactions. The frequency is not known. If other adverse reactions not mentioned above occur, a doctor or a qualified health care professional 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

14 January 2009