



London, 14 January 2009  
Doc. Ref.: EMEA/HMPC/579636/2008

**COMMITTEE ON HERBAL MEDICINAL PRODUCTS  
(HMPC)**

**DRAFT**

**COMMUNITY HERBAL MONOGRAPH ON  
*TARAXACUM OFFICINALE* WEBER ex WIGG., FOLIUM**

<b>DISCUSSION IN WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (MLWP)</b>	November 2008 January 2009
<b>ADOPTION BY HMPC FOR RELEASE FOR CONSULTATION</b>	14 January 2009
<b>END OF CONSULTATION (DEADLINE FOR COMMENTS)</b>	15 May 2009
<b>REDISCUSSION IN WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (MLWP)</b>	
<b>ADOPTION BY HMPC</b>	

Comments should be provided using this [template](#) to [hmpc.secretariat@emea.europa.eu](mailto:hmpc.secretariat@emea.europa.eu)  
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**KEYWORDS**

Herbal medicinal products; HMPC; Community herbal monographs; traditional use; *Taraxacum officinale* Weber ex Wigg.; Taraxaci folium; dandelion leaf

**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<sup>1</sup>**

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

**3. PHARMACEUTICAL FORM**

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

<sup>1</sup> The declaration of the active substance(s) for an individual finished product should be in relevance with the relevant herbal quality guidance..

<sup>2</sup> The material complies with Ph. Eur. monograph on herbal drugs.

#### 4. CLINICAL PARTICULARS

##### 4.1. Therapeutic indications

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

##### 4.2. Posology and method of administration

<u>Well-established use</u>	<u>Traditional use</u>
	<p><b>Posology</b></p> <p><i>Adolescents over 12 years of age, adults</i></p> <p>a) Liquid extract (1:1 in 25% ethanol), 4-10 ml 3 times daily</p> <p>b) Expressed juice from fresh <i>Taraxaci folium</i>, 2 times daily</p> <p>c) Dried leaves, comminuted: 3 times daily as tea (4-10 g)</p> <p>The use is not recommended in children under 12 years of age (see also 4.4 'Special warnings and precautions for use').</p> <p><b>Duration of use</b></p> <p>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.</p> <p><b>Method of administration</b></p> <p>Oral use.</p> <p>To ensure an increase of the amount of urine, adequate fluid intake is required during treatment.</p>

#### 4.3. Contraindications

<u>Well-established use</u>	<u>Traditional use</u>
	Hypersensitivity to the active substance or to plants of the Asteraceae (Compositae) family.

#### 4.4. Special warnings and precautions for use

<u>Well-established use</u>	<u>Traditional use</u>
	<p>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.</p> <p>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.</p> <p>The use in children under 12 years of age is not recommended because of the lack of available experience.</p> <p>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.</p>

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

<u>Well-established use</u>	<u>Traditional use</u>
	None reported.

#### 4.6. Pregnancy and lactation

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

#### 4.7. Effects on ability to drive and use machines

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

#### 4.8. Undesirable effects

<u>Well-established use</u>	<u>Traditional use</u>
	Allergic reactions. 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

<u>Well-established use</u>	<u>Traditional use</u>
	No case of overdose has been reported.

### 5. PHARMACOLOGICAL PROPERTIES

#### 5.1. Pharmacodynamic properties

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

#### 5.2. Pharmacokinetic properties

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

#### 5.3. Preclinical safety data

<u>Well-established use</u>	<u>Traditional use</u>
	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**

<u>Well-established use</u>	<u>Traditional use</u>
	Not applicable.

**7. DATE OF COMPILATION/LAST REVISION**

14 January 2009