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SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

European Union herbal monograph on *Taraxacum officinale* F.H. Wigg., radix

Draft

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<p>BG (bulgarski): Глухарче, корен CS (čeština): smetánkový kořen DA (dansk): Mælkebøtterod DE (Deutsch): Löwenzahnwurzel EL (elliniká): ταραξάκου ρίζα EN (English): dandelion root ES (español): diente de león, parte aérea y raíz de ET (eesti keel): võilillejuur FI (suomi): voikukka, juuri FR (français): racine de pissenlit HR (hrvatski): maslačkov korijen HU (magyar): pitypang gyökér IT (italiano): Tarassaco. radice</p>	<p>LT (lietuvių kalba): Kiaulpienių šaknys LV (latviešu valoda): Pienenes sakne MT (Malti): għerq iċ-ċikwejra salvaġġa NL (Nederlands): Paardenbloem wortel PL (polski): Korzeń mniszka PT (português): Taráxaco, raiz RO (română): radacină de păpădie SK (slovenčina): koreň púpavy SL (slovenščina): korenina navadnega regrata SV (svenska): maskros, rot IS (íslenska): túnfífill rót NO (norsk): Løvetannrot</p>
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European Union herbal monograph on *Taraxacum officinale* F.H. Wigg., radix

1. Name of the medicinal product

To be specified for the individual finished product.

2. Qualitative and quantitative composition^{1, 2}

Well-established use	Traditional use
	<p>With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended.</p> <p><i>Taraxacum officinale</i> F.H. Wigg., radix (dandelion root).</p> <p>i) Herbal substance</p> <p>Not applicable.</p> <p>ii) Herbal preparations</p> <p>a) Comminuted dried root</p> <p>b) Expressed juice (DER 1:1) from fresh root boiled in ethanol</p> <p>c) Juice from fresh root</p> <p>d) Liquid extract (DER 1:1), extraction solvent ethanol 30% (V/V)</p> <p>e) Tincture (ratio of herbal substance to extraction solvent 1:5), extraction solvent ethanol 45% (V/V)</p>

3. Pharmaceutical form

Well-established use	Traditional use
	<p>Herbal preparations in liquid dosage form for oral use.</p> <p>Comminuted herbal substance as herbal tea for oral use.</p> <p>The pharmaceutical form should be described by</p>

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 with the Ph. Eur. monograph (ref.: 1852).

Well-established use	Traditional use
	the European Pharmacopoeia full standard term.

4. Clinical particulars

4.1. Therapeutic indications

Well-established use	Traditional use
	<p>Indication 1)</p> <p>Traditional herbal medicinal product used for the relief of symptoms related to mild digestive disorders (such as feeling of abdominal fullness, flatulence, and slow digestion).</p> <p>Indication 2)</p> <p>Traditional herbal medicinal product for temporary loss of appetite.</p> <p>Indication 3)</p> <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 indications exclusively based upon long-standing use.</p>

4.2. Posology and method of administration³

Well-established use	Traditional use
	<p>Posology</p> <p>Adolescents, adults and elderly.</p> <p>Indications 1), 2) and 3)</p> <p>a) Comminuted herbal substance for decoction: single dose of 3 - 5 g in 150 ml of water, 2 - 3 times daily</p> <p>b) Expressed juice (DER 1:1) from fresh root boiled with ethanol. Single dose 5 ml, diluted in small volume of water, 3 times daily</p>

³ For guidance on herbal substance/herbal preparation administered as herbal tea or as infusion/decoction/macerate preparation, please refer to the HMPC 'Glossary on herbal teas' (EMA/HMPC/5829/2010 Rev.1).

Well-established use	Traditional use
	<p data-bbox="810 250 970 277">Indication 1)</p> <p data-bbox="820 304 1394 362">c) Juice from fresh root. Single dose 4 - 8 ml, three times daily</p> <p data-bbox="810 389 1072 416">Indications 1) and 3)</p> <p data-bbox="820 443 1401 537">d) Liquid extract (DER 1:1), extraction solvent ethanol 30% (V/V). Single dose 2 - 8 ml, three times daily</p> <p data-bbox="820 564 1385 689">e) Tincture (ratio of herbal substance to extraction solvent 1:5), extraction solvent ethanol 45% (V/V). Single dose 5 - 10 ml, three times daily</p> <p data-bbox="810 716 1394 824">The use in children under 12 years of age is not recommended (see section 4.4 'Special warnings and precautions for use').</p> <p data-bbox="810 851 1024 878">Duration of use</p> <p data-bbox="810 904 1359 1048">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 data-bbox="810 1075 1155 1102">Method of administration</p> <p data-bbox="810 1128 922 1155">Oral use.</p> <p data-bbox="810 1182 970 1209">Indication 2)</p> <p data-bbox="810 1236 1343 1308">Preparations are to be taken ½ hour before meal.</p> <p data-bbox="810 1335 970 1361">Indication 3)</p> <p data-bbox="810 1388 1372 1496">To ensure an increase of the amount of urine, adequate fluid intake is required during treatment.</p>

4.3. Contraindications

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

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	Indication 1), 2), 3):

Well-established use	Traditional use
	<p>Due to possible stimulation on bile secretion dandelion root is not recommended in case of obstruction of the bile duct, cholangitis, liver disease, gallstones and any other biliary diseases.</p> <p>The use in children under 12 years of age has not been established due to lack of adequate data.</p> <p>Indication 3):</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> <p>Conditions where a reduced fluid intake is recommended (e.g. severe cardiac or renal disease).</p> <p>For preparations 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>

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

Well-established use	Traditional use
	None reported.

4.6. Fertility, pregnancy and lactation

Well-established use	Traditional use
	<p>Safety during pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy and lactation is not recommended.</p> <p>No fertility data available.</p>

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. Tests on reproductive toxicity, genotoxicity and carcinogenicity have not been performed.

6. Pharmaceutical particulars

Well-established use	Traditional use
	Not applicable.

7. Date of compilation/last revision

05 May 2021