EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

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

Final

Initial assessment	
Discussion in Committee on Herbal Medicinal Products (HMPC)	September 2020 November 2020 January 2021 May 2021
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End of consultation (deadline for comments[1]).	31 August 2021
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Adoption by HMPC	24 November 2021

Keywords	Herbal medicinal products; HMPC; European Union herbal monographs; traditional use; *Taraxacum officinale* F.H. Wigg., radix; Taraxaci officinalis radix; Dandelion root

[1] No comments were received during the period of public consultation. Therefore, the final monograph is published together with the final assessment report and list of references, without an 'Overview of comments received during the public consultation'.

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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[2, 3]

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

3. Pharmaceutical form

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

[2] The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance.

[3] The material complies with the Ph. Eur. monograph (ref.: 1852).

4. Clinical particulars

4.1. Therapeutic indications

Well-established use	Traditional use
	Indication 1) 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). Indication 2) Traditional herbal medicinal product for temporary loss of appetite. Indication 3) 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 indications exclusively based upon long-standing use.

4.2. Posology and method of administration[4]

Well-established use	Traditional use
Posology	**Posology** *Adolescents, adults and elderly* Indications 1), 2) and 3) a) Comminuted herbal substance for decoction: single dose of 1-5 g in 150 ml of water, 2-3 times daily b) Expressed juice (DER 1:1) from fresh root subjected to a steam of ethanol: single dose 5 ml, diluted in small volume of water, 3 times daily Indication 1) and 3) c) Juice from fresh root: single dose 4-8 ml, 3 times daily

[4] 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
	d) Liquid extract (DER 1:1), extraction solvent ethanol 30% V/V: single dose 2-8 ml, 3 times daily e) Tincture (ratio of herbal substance to extraction solvent 1:5), extraction solvent ethanol 45% V/V: single dose 5-10 ml, 3 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. Indication 2) Preparations are to be taken ½ hour before meal. Indication 3) To ensure an increase of the amount of urine, adequate fluid intake is required during treatment (see section 4.4. Special warnings and precautions for use).

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) and 3) Due to possible stimulation on bile secretion, dandelion root is not recommended in case of

Well-established use	Traditional use
	obstruction of the bile duct, cholangitis, liver disease, gallstones and any other biliary diseases. The use in children under 12 years of age has not been established due to lack of adequate data. Indication 3) 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. Because adequate fluid intake is required during treatment (see section 4.2. Posology and method of administration), dandelion root is not recommended for patients with conditions where reduced fluid intake is advised by a medical doctor. 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.

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
	Safety during pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy and lactation is not recommended. No fertility data available.

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.

5.2. Pharmacokinetic properties

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

5.3. Preclinical safety data

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

24 November 2021