



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

22 September 2021
EMA/HMPC/489142/2020
Committee on Herbal Medicinal Products (HMPC)

European Union herbal monograph on *Centella asiatica* (L.) Urb., herba

Draft

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BG (bulgarski): Азиатска центела, стрък	LT (lietuvių kalba): Azijinių centelių žolė
CS (čeština): nař centely asijské	LV (latviešu valoda): Centelas laksti
DA (dansk): Centellaurt	MT (Malti): centella
DE (Deutsch): Asiatisches Wassernabelkraut	NL (Nederlands): Centella
EL (elliniká): κεντέλλης ασιατικής (υδροκότυλο ασιατικό)	PL (polski): Ziele wąkroty azjatyckiej
EN (English): Centella	PT (português): centela
ES (español): centella, partes aéreas de	RO (română): iarbă de centella asiatica
ET (eesti keel): vesinabaürt	SK (slovenčina): vňař centely ázijskej
FI (suomi): rohtosammakonputki, verso	SL (slovenščina): zel azijskega navadnega popnjaka
FR (français): hydrocotyle (parties aériennes d')	SV (svenska): sallatsspikblad, ört
HR (hrvatski): centelina zelen	<i>IS (íslenska):</i>
HU (magyar): ázsiái gázló virágos hajtás	<i>NO (norsk): centella</i>
IT (italiano): Centella parti aeree	

European Union herbal monograph on *Centella asiatica* (L.) Urb., herba

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
	With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended <i>Centella asiatica</i> (L.) Urb., herba (Centella) i) Herbal substance Not applicable ii) Herbal preparations a) Comminuted herbal substance b) Powdered herbal substance

3. Pharmaceutical form

Well-established use	Traditional use
	Comminuted herbal substance as an infusion for cutaneous use. Powdered herbal substance for cutaneous 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
	Traditional herbal medicinal product used to aid in healing of minor wounds.

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.: 1498)

Well-established use	Traditional use
	The product is a traditional herbal medicinal product for use in specified indication exclusively based upon long-standing use.

4.2. Posology and method of administration ³

Well-established use	Traditional use
	<p>Posology</p> <p><i>Adults and Elderly</i></p> <p>a) Comminuted herbal substance as an infusion for cutaneous use: 0.6 g of comminuted herbal substance in small amount of boiling water to be applied on the affected area 3 times daily. Daily dose: 1.8 g</p> <p>b) Single dose: 0.6 g three times daily to be applied on the affected area Daily dose: 1.8 g</p> <p>The use in children and adolescents under 18 years of age is not recommended (see section 4.4 'Special warnings and precautions for use').</p> <p>Duration of use</p> <p>Not to be used for more than 1 week.</p> <p>If the symptoms persist during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p> <p>Method of administration</p> <p>Cutaneous use.</p> <p>Preparation a) The still warm infusion is used to prepare impregnated dressings.</p> <p>Preparation b) As cutaneous powder.</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).

4.3. Contraindications

Well-established use	Traditional use
	Hypersensitivity to the active substance and to other plants of the Apiaceae (Umbeliferae) family.

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	<p>The use in children and adolescents under 18 years of age has not been established due to lack of adequate data.</p> <p>If the symptoms worsen 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

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.</p> <p>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
	None known.

Well-established use	Traditional use
	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 and carcinogenicity have not been performed.

6. Pharmaceutical particulars

Well-established use	Traditional use
	Not applicable.

7. Date of compilation/last revision

22 September 2021