30 March 2022
EMA/HMPC/489142/2020
Committee on Herbal Medicinal Products (HMPC)

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

Final

Initial assessment	
Discussion in Monograph and List Working Party (MLWP)	May 2009 July 2009 September 2009
Adoption by HMPC for release for consultation	17 September 2009
End of consultation (deadline for comments).	15 January 2010
Discussion and Agreement by MLWP	September 2010 November 2010
Adoption by Committee on Herbal Medicinal Products (HMPC) Public statement (EMA/HMPC/579663/2009) Assessment Report (EMA/HMPC/291177/2009) List of references (EMEA/HMPC/456740/2006) Overview of comments received during the public consultation (EMEA/HMPC/200856/2007) HMPC Opinion (EMEA/HMPC/280039/2007)	25 November 2010
First systematic review	
Discussion in HMPC	March 2020 November 2020 January 2021 May 2021 July 2021 September 2021
Adopted by HMPC for release for consultation	22 September 2021
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Adoption by HMPC Monograph (EMA/HMPC/489142/2020) AR (EMA/HMPC/489140/2020)	30 March 2022

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

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Keywords	Herbal medicinal products; HMPC; European Union herbal monographs; traditional use; *Centella asiatica* (L.) Urb., herba; Centellae asiaticae herba; Centella

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

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 *Centella asiatica* (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. The product is a traditional herbal medicinal

[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
	product for use in the specified indication exclusively based upon long-standing use.

4.2. Posology and method of administration [3]

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

[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
	The use in children and adolescents under 18 years of age has not been established due to lack of adequate data. If the symptoms worsen 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. 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
	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.

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. 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

30 March 2022