19 March 2025
EMA/HMPC/150763/2015
Committee on Herbal Medicinal Products (HMPC)

European Union herbal monograph on *Cistus creticus* L., herba

Final

Initial assessment	
Discussion in Working Party on European Union monographs and European Union list (MLWP) / Committee on Herbal Medicinal Products (HMPC)	January 2015 March 2015 May 2015 July 2015 September 2015 November 2015 February 2016 September 2016 January 2021 March 2021 May 2021 July 2021 November 2021 November 2022 January 2023 May 2023 January 2024 March 2024 May 2024 July 2024
Adopted by HMPC for release for consultation	24 July 2024
Start of public consultation	15 August 2024
End of consultation (deadline for comments)	15 November 2024
Re-discussion in HMPC	January 2025 March 2025
Adoption by HMPC	19 March 2025

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

Keywords	Committee on Herbal Medicinal Products; HMPC; European Union herbal monograph; herbal medicinal products, traditional herbal medicinal products; traditional use; *Cistus creticus* L., herba; Cisti cretici herba; pink rock-rose

BG (bulgarski): Памуклийка, лист	LT (lietuvių kalba): Žilųjų švitrūnų lapai
CS (čeština): nať cistu krétského	LV (latviešu valoda): Krētas klinšrozes lapa
DA (dansk): Kretensisk soløjetræblad	MT (Malti): weraq tal-ward tal-blat
DE (Deutsch): Zistrosenkraut	NL (Nederlands): Cistusroos, blad/hars (labdanum)
EL (elliniká): κίστου του κρητικού πόα	PL (polski): Liść czystka kreteńskiego
EN (English): Pink rock-rose	PT (português): cistus-creticus, folhas
ES (español): jara de creta (menorca), hoja de	RO (română): frunză de *Cistus creticus*
ET (eesti keel): mürri-kiviroosikuleht	SK (slovenčina): vňať cistusu krétskeho
FI (suomi): kreetankistus, verso	SL (slovenščina): zel kretskega brškina
FR (français): ciste de Crète	SV (svenska): kretacistros, ört
HR (hrvatski): list kretskog bušina	IS (íslenska):
HU (magyar): krétai szuhar levél	NO (norsk): kretasolroseblad
IT (italiano): Cisto di Creta, parti aeree	

European Union herbal monograph on *Cistus creticus* L., herba

1. Name of the medicinal product

To be specified for the individual finished product.

2. Qualitative and quantitative composition[1]

Well-established use	Traditional use
	With regard to the registration application of Article 16d(1) of Directive 2001/83/EC *Cistus creticus* L., herba (pink rock-rose) i) Herbal substance Not applicable. ii) Herbal preparations Comminuted herbal substance

3. Pharmaceutical form

Well-established use	Traditional use
	Herbal preparation as decoction for oral 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 for relief of cough associated with cold. The product is a traditional herbal medicinal product for use in the specified indications exclusively based upon long-standing use.

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

4.2. Posology and method of administration[2]

Well-established use	Traditional use
Method of administration	**Posology** *Adults and elderly* Single dose Herbal tea: 10 g of the comminuted herbal substance in 200 ml of water as a decoction, 1-3 times daily. Decoction should be brought to the boil till remaining 100 ml (approx. 20 minutes). Daily dose: 10-30 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** If the symptoms persist longer than 1 week during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted. **Method of administration** Oral use.

4.3. Contraindications

Well-established use	Traditional use
	Hypersensitivity to the active substance.

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 dyspnoea, fever or purulent sputum occurs, during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.

[2] 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).

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. If adverse reactions 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

19 March 2025