24 July 2024
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Committee on Herbal Medicinal Products (HMPC)

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

Draft

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

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[1] a) Comminuted herbal substance

3. Pharmaceutical form

Well-established use	Traditional use
	Comminuted herbal substance as herbal tea (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 in 200 ml of boiling water as a decoction, 1-3 times daily. Decoction should be brought to the boil till remaining 100 ml(approx. 20 minutes). Daily dose: 10-30g 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 Rev.1).

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

24 July 2024