



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

29 May 2024
EMA/HMPC/379866/2023
Committee on Herbal Medicinal Products (HMPC)

European Union herbal monograph on *Prunus avium* L.; *Prunus cerasus* L., peduncle

Draft

Initial assessment	
Discussion in Committee on Herbal Medicinal Products (HMPC)	September 2023 November 2023 January 2024 March 2024 May 2024
Adopted by HMPC for release for consultation	29 May 2024
Start of public consultation	15 June 2024
End of consultation (deadline for comments). Comments should be provided using this template to hmpc.secretariat@ema.europa.eu	15 September 2024

Keywords	Herbal medicinal products; HMPC; European Union herbal monographs; traditional use; <i>Prunus avium</i> L., peduncle; <i>Prunus cerasus</i> L., peduncle; Cherry stalks
----------	---



BG (bulgarski): Вишни, дръжки	LT (lietuvių kalba): Atsikosėjimą gerinantis mišinys
CS (čeština): Třešňové a višňové stopky	LV (latviešu valoda): Ķiršu kātiņš
DA (dansk): Kirsebærstilke	MT (Malti): zkuk taċ-ċirasa salvaġġa
DE (Deutsch): Sauerkirschstiele / Süßkirschstiele	NL (Nederlands): Kersensteel
EL (elliniká): Κερσεάς / Βυσσινέας μίσχος	PL (polski): szypułki wiśni/czereśni (ogonki wiśni/czereśni)
EN (English): Cherry stalks	PT (português): cereja, pedúnculos
ES (español): guindo, pedúnculos de	RO (română): codițe de cirese
ET (eesti keel):	SK (slovenčina): stopky višne/stopky čerešne
FI (suomi): kirsikka, varsi	SL (slovenščina): peclji ploda češnje
FR (français): cerise (queue de)	SV (svenska): körsbär, stjälk
HR (hrvatski): peteljke divlje trešnje	IS (íslenska):
HU (magyar): meggy kocsány	NO (norsk): Surkirsebærstilker/Morellstilker
IT (italiano): Amareno, peduncolo	

European Union herbal monograph on *Prunus avium* L.; *Prunus avium* L., peduncle

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 <i>Prunus avium</i> L., and/or <i>Prunus cerasus</i> L., peduncle (cherry stalks) i) Herbal substance Not applicable. ii) Herbal preparations Comminuted herbal substance.

3. Pharmaceutical form

Well-established use	Traditional use
	Herbal preparation as herbal tea 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 the relief of symptoms associated with minor urinary tract complaints in addition to the general

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

² Detailed specifications for the herbal substance shall be given by references to bibliographic sources in absence of a monograph in the European Pharmacopoeia, a national pharmacopoeia or national codex currently used officially in a Member State.

	<p>recommendation of a sufficient fluid intake to increase the amount of urine.</p> <p>The product is a traditional herbal medicinal product for use in the specified indication exclusively based upon long-standing use.</p>
--	--

4.2. Posology and method of administration³

Well-established use	Traditional use
	<p>Posology</p> <p><i>Adults and Elderly</i></p> <p>2-6 g of comminuted herbal substance in 200 mL water as an infusion or decoction.</p> <p>2-4 times daily.</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>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.</p> <p>Method of administration</p> <p>Oral use.</p>

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
	<p>The use in children under 18 years of age has not been established due to lack of adequate data.</p> <p>If urinary tract complaints worsen and symptoms such as fever, dysuria, spasm, or blood in the urine occur during the use of medicinal product, a doctor</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).

	<p>or a qualified health care practitioner should be consulted.</p> <p>Because adequate fluid intake is required during treatment (see section 4.2. Posology and method of administration), <i>Prunus avium</i> L. and/or <i>Prunus cerasus</i> L., peduncle is not recommended for patients with conditions where reduced fluid intake is advised by a medical doctor.</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. 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
	<p>None known.</p> <p>If adverse reactions occur, a doctor or a qualified health care practitioner should be consulted.</p>

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
	<p>Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC, unless necessary for the safe use of the product.</p> <p>Adequate tests on reproductive toxicity, genotoxicity and carcinogenicity have not been performed.</p>

6. Pharmaceutical particulars

Well-established use	Traditional use
	Not applicable.

7. Date of compilation/last revision

29 May 2024