20 September 2023
EMA/HMPC/648100/2022
Committee on Herbal Medicinal Products (HMPC)

European Union herbal monograph on *Pelargonium sidoides* DC; *Pelargonium reniforme* Curt., radix

Draft - Revision 2

Initial assessment	
Discussion in Working Party on Community monographs and Community list (MLWP)	September 2010 November 2010 January 2011 March 2011
Adopted by Committee on Herbal Medicinal Products (HMPC) for release for consultation	31 March 2011
End of consultation (deadline for comments).	15 August 2011
Re-discussion in MLWP	September 2011 November 2011 January 2012 May 2012
Adoption by HMPC Monograph (EMEA/HMPC/560961/2010) Assessment report (EMEA/HMPC/560962/2010) List of references (EMEA/HMPC/560963/2010) Overview of comments received during the public consultation (EMEA/HMPC/748350/2011) HMPC Opinion (EMEA/HMPC/742263/2012)	20 November 2012
First revision	
Discussion in MLWP	September 2014 July 2015
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End of consultation (deadline for comments[1])	31 January 2016
Re-discussion in MLWP	April 2016 May/June 2016 July 2016 November 2016 March 2017 May 2017 July 2017 September 2017 November 2017 January 2017 March 2018
Adoption by HMPC	05 June 2018
Second revision	
Discussion in HMPC	March 2022 May 2022 July 2022 September 2022 January 2023 March 2023 May 2023 July 2023 September 2023
Adopted by HMPC for release for consultation	20 September 2023
End of consultation (deadline for comments)	15 January 2024

Keywords	Herbal medicinal products; HMPC; EU herbal monographs; traditional use; *Pelargonium sidoides* DC; *Pelargonium reniforme* Curt., radix; Pelargonii radix; pelargonium root

[1] No comments were received during the period of public consultation. Therefore the final monograph is published together with the final assessment report and list of references, without an 'Overview of comments received during the public consultation'.

BG (bălgarski): Пеларгониум, корен	LT (lietuvių kalba): Pelargonijų šaknys
CS (čeština): pelargoniový kořen	LV (latviešu valoda): Pelargonijas saknes
DA (dansk): Pelargonierod	MT (malti): għerq tal-ġeranju
DE (Deutsch): Pelargoniumwurzel	NL (nederlands): Geranium
EL (elliniká): πελαργονίου ρίζα	PL (polski): Korzeń pelargonii
EN (English): pelargonium root	PT (português): pelargónio, raiz
ES (espanol): pelargonio, raíz de	RO (română): rădăcină de muscata
ET (eesti keel): pelargoonijuur	SK (slovenčina): koreň muškátu
FI (suomi): pelargoni, juuri	SL (slovenščina): korenina pelargonije
FR (français): pélargonium (racine de)	SV (svenska): pelargon, rot
HU (magyar): muskátligyökér	*IS (íslenska)*:
IT (italiano): Pelargonio radice	*NO (norsk):* pelargoniumrot

European Union herbal monograph on *Pelargonium sidoides* DC; *Pelargonium reniforme* Curt., radix

1. Name of the medicinal product

To be specified for the individual finished product.

2. Qualitative and quantitative composition[2, 3]

Well-established use	Traditional use
	With regard to the registration application of Article 16d (1) of Directive 2001/83/EC *Pelargonium sidoides* DC and/or *Pelargonium reniforme* Curt., radix (pelargonium root) i) Herbal substance Not applicable ii) Herbal preparations a) Liquid extract (DER 1:8-10), extraction solvent ethanol 11% (m/m) b) Dry extract (DER 4-25:1), extraction solvent ethanol 11% (m/m) c) Dry extract (DER 4-7:1), extraction solvent ethanol 14% (V/V)

3. Pharmaceutical form

Well-established use	Traditional use
	Herbal preparations in liquid or solid dosage forms for oral use. The pharmaceutical form should be described by the European Pharmacopoeia full standard term.

4. Clinical particulars

4.1. Therapeutic indications

[2] The material complies with the Ph. Eur. monograph (ref.: 2264).
[3] The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance.

Well-established use	Traditional use
	Traditional herbal medicinal product for the symptomatic treatment of common cold. The product is a traditional herbal medicinal product for use in the specified indication exclusively based upon long-standing use.

4.2. Posology and method of administration

Well-established use	Traditional use
	Posology Herbal preparation a) *Adolescents over the age of 12 years, adults and elderly* Single dose: 1.4 ml, 3 times daily Daily dose: 4.2 ml *Children between 6-12 years* Single dose: 0.9 ml, 3 times daily Daily dose: 2.7 ml *Children between 3 and 5 years* Single dose: 0.4 ml, 3 times daily Daily dose: 1.2 ml Herbal preparations b) and c) *Adolescents over the age of 12 years, adults and elderly* Single dose: 20 mg, 3 times daily Daily dose: 60 mg *Children between 6-12 years* Single dose: 13.3 mg, 3 times daily; or 20 mg, 2 times daily Daily dose: 40 mg *Children between 3 and 5 years* Single dose: 6.67 mg, 3 times daily Daily dose: 20 mg **Herbal preparations a-c)** The use in children under 3 years of age is not

Well-established use	Traditional use
	recommended (see section 4.4 'Special warnings and precautions for use'). **Herbal preparations b-c)** The herbal preparations b) and c) should be given to children under 6 years only in liquid dosage forms. **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(s).

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	The oral use in children under 3 years of age is not recommended because of concerns requiring medical advice. Hepatotoxicity and hepatitis cases were reported in association with the administration of the medicinal product. In case signs of hepatotoxicity occur, the administration of the medicinal product should be stopped immediately, and a medical doctor should be consulted. If the symptoms worsen during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted. For liquid extracts containing ethanol, the appropriate labelling for ethanol, taken from the 'Guideline on excipients in the label and package leaflet of medicinal products for human use', must be included.

4.5. Interactions with other medicinal products and other forms of interaction

Well-established use	Traditional use
	None reported

4.6. Pregnancy and lactation

Well-established use	Traditional use
	No fertility data available. Safety during pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy and lactation is not recommended.

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
	Immune system disorders: Hypersensitivity, (anaphylactic reaction). The frequency is not known. Skin and subcutaneous tissue disorders: Rash, pruritus, urticaria, angioedema. The frequency is not known. Respiratory, thoracic and mediastinal disorders: Nasal bleeding. The frequency is not known. Gastrointestinal disorders: Diarrhoea, epigastric pain, nausea, vomiting, gingival bleeding. The frequency is not known. Hepatobiliary disorders: Hepatotoxicity, hepatitis. The frequency is not known. 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. Tests on reproductive toxicity, genotoxicity and carcinogenicity are not available.

6. Pharmaceutical particulars

Well-established use	Traditional use
	Not applicable.

7. Date of compilation/last revision

20 September 2023