29 September 2015
EMA/HMPC/444244/2015
Committee on Herbal Medicinal Products (HMPC)

European Union herbal monograph on *Pelargonium sidoides* DC and/or *Pelargonium reniforme* Curt., radix

Draft

Initial assessment	
Discussion in Working Party on European Union monographs and list (MLWP)	September 2010 November 2010 January 2011 March 2011
Adoption by Committee on Herbal Medicinal Products (HMPC) for release for consultation	31 March 2011
End of consultation (deadline for comments). Comments should be provided using this template to hmpc.secretariat@ema.europa.eu	15 August 2011
Re-discussion in MLWP	September 2011 November 2011 January 2012 May 2012
Adoption by HMPC	20 November 2012
First review	
Discussion in MLWP	September 2014 July 2015
Adoption by HMPC for release for consultation	29 September 2015
Start of public consultation	26 October 2015
End of consultation (deadline for comments). Comments should be provided using this template to hmpc.secretariat@ema.europa.eu	31 January 2016

Note: A 'Review for specific reasons' (see RP EMA/HMPC/326440/2007 Rev.2) had been triggered by new scientific data available to the HMPC (re-evaluation of the Validity of the Bronchitis Severity Scale BSS, see meeting report May 2013 EMA/HMPC/301544/2013). Although no changes were introduced in the monograph, a public consultation was considered useful after careful new assessment of scientific data (in relation to the additional document made available since the primary assessment) as reflected

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in the revised draft AR (amendments to the relevant section 4). Interested parties are given the opportunity to comment before finalisation.

Keywords	Herbal medicinal products; HMPC; European Union herbal monographs; traditional use; *Pelargonium sidoides* DC and/or *Pelargonium reniforme* Curt., radix; Pelargonii radix; Pelargonium root

BG (bulgarski): 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 (español): Pelargonio, raíz de	RO (română):
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
HR (hrvatski): pelargonijin korijen	*IS (íslenska)*:
HU (magyar): muskátligyökér	*NO (norsk):* Pelargoniumrot
IT (italiano): Pelargonio radice	

European Union herbal monograph on *Pelargonium sidoides* DC and/or *Pelargonium reniforme* Curt., radix

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 as amended *Pelargonium sidoides* DC and/or *Pelargonium reniforme* Curt., radix (Pelargonium root) i) Herbal substance Not applicable. ii) Herbal preparations Liquid extract (DER 1:8-10), extraction solvent ethanol 11% (m/m) Dry extract, (DER 4-25:1), extraction solvent ethanol 11% (m/m)

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

Well-established use	Traditional use
	Traditional herbal medicinal product for the

[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.: 2008).

Well-established use	Traditional use
	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 *Adolescents over the age of 12 years, adults and elderly* Single dose a) Liquid extract: 1.19-1.25 ml, 3 times daily b) Dry extract: 20 mg, 3 times daily *Children between 6-12 years* a) Liquid extract: 0.79-0.83 ml, 3 times daily b) Dry extract: 20 mg, 2 times daily The use in children under 6 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(s).

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	The use in children under 6 years of age has not

Well-established use	Traditional use
	been established due to lack of adequate data. 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. 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
	Mild gastrointestinal complaints (diarrhea, epigastric discomfort, nausea or vomiting, dysphagia), mild nasal and gingival bleeding and allergic reactions have been reported. The frequency was very rare. Hepatotoxicity has been reported. 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 as amended.

5.2. Pharmacokinetic properties

Well-established use	Traditional use
	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.

5.3. Preclinical safety data

Well-established use	Traditional use
	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended, unless necessary for the safe use of the product. Adequate 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

29 September 2015