



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/HMPC/378804/2018
EMA/HMPC/M/H/0225
Committee on Herbal Medicinal Products (HMPC)

Opinion of the HMPC on a European Union herbal monograph on *Pelargonium sidoides* DC and/or *Pelargonium reniforme* Curt., radix

This document was valid from 05 June 2018 until 29 May 2024.

The HMPC, in accordance with Article 16h(3) of Directive 2001/83/EC and as set out in the appended assessment report, establishes, by a majority of 23 out of 25 votes a European Union herbal monograph on *Pelargonium sidoides* DC and/or *Pelargonium reniforme* Curt., radix which is set out in Annex I.

The divergent positions are appended to this opinion.

The Norwegian HMPC member was not present during the meeting.

This opinion is forwarded to Member States, to Iceland and Norway, together with its Annex I and appendices.

The European Union herbal monograph and assessment report will be published on the European Medicines Agency website. They replace those adopted on 20 November 2012.

London, 5 June 2018



**Annex I: European Union herbal monograph
(EMA/HMPC/444244/2015)**

Superseded

Appendix I: Assessment report (EMA/HMPC/444251/2015)

Superseded

Appendix II: Divergent positions

Superseded

The member of the HMPC mentioned below did not agree with the HMPC's opinion for the following reason:

The criteria for WEU are regarded fulfilled. Comparable clinical data has been accepted for other herbal preparations in the same therapeutic area.

Astrid Obmann, HMPC alternate member from Austria

London, 5 June 2018



Superseded

The member of the HMPC mentioned below did not agree with the HMPC's opinion for the following reason:

Products manufactured from *Pelargonium radix* have been reported to exert toxic liver effects. Warnings in the monograph concerning liver symptoms do not exclude risk to the patient, as liver diseases usually induce symptoms only at late stage of the disease, when liver damage may be irreversible.

As the proposed indication, i.e. symptomatic treatment of common cold, is not a life-threatening disease, any risk of severe adverse reactions is not regarded acceptable. Therefore, the benefit to risk ratio is deemed negative.



Eeva Sofia Leinonen, HMPC Member from Finland

London, 5 June 2018