



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

EMA/HMPC/319732/2024  
EMA/HMPC/M/H/0269  
Committee on Herbal Medicinal Products (HMPC)

## Opinion of the HMPC on a European Union herbal monograph on *Pelargonium sidoides* DC; *Pelargonium reniforme* Curt., radix

### Opinion

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 27 votes a revised European Union herbal monograph on *Pelargonium sidoides* DC; *Pelargonium reniforme* Curt., radix which is set out in Annex I.

The divergent positions are appended to this opinion.

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

The revised European Union herbal monograph and assessment report will be published on the European Medicines Agency website. They replace those adopted on 05 June 2018.

Amsterdam, 29 May 2024.

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# **Annex I: European Union herbal monograph (EMA/HMPC/648100/2022)**

# Appendix I: Assessment report (EMA/HMPC/765656/2022)

## Appendix II: Divergent positions

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

Finland does not agree on the *Pelargonium* monograph 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 a 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.

Maria Paile-Hyvärinen, HMPC member from Finland.

Amsterdam, 29 May 2024.

Ireland does not support the proposed EU herbal monograph for *Pelargonium radix*. We do not support the use in children <12 years as this is not appropriate for self-medication in this population. This is in line with our nationally approved THMPs.

Jackie Masterson, HMPC member from Ireland.

Amsterdam, 29 May 2024.

Italy has a divergent opinion on the HMPC's position on the EU herbal monograph on *Pelargonium sidoides* DC; *Pelargonium reniforme* Curt., radix with regard to the traditional use, due to the potential risk of hepatotoxicity in children between 3-5 years of age. Indeed, there is not sufficient evidence on the risk of hepatotoxicity to consider the use of *pelargonium* safe in children under 6 years of age, since in this age group the metabolic processes are not fully mature. Furthermore, the exposure of these patients to *pelargonium* appears unjustified considering the benign and self-limiting nature of the condition to be treated.

Therefore, based on the above considerations, the establishment of a monograph on the traditional use of *Pelargonium sidoides* DC; *Pelargonium reniforme* Curt., radix which includes the use in children below 6 years of age cannot be supported as the requirements related to an acceptable level of safety according to the Directive 2004/24/EC are not fulfilled.

Alessandro Assisi, HMPC member from Italy.

Amsterdam, 29 May 2024.

The Netherlands does not support the revised EU herbal monograph on *Pelargonium sidoides* DC; *Pelargonium reniforme* Curt., radix, because there is insufficient evidence to support the safe use by children below 6 years for the proposed indication.

Burt Kroes, HMPC member from the Netherlands.

Amsterdam, 29 May 2024.