



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/HMPC/531448/2016
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Committee on Herbal Medicinal Products (HMPC)

Opinion of the HMPC on a European Union herbal monograph on *Origanum majorana* L., herba

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 27 out of 28 votes a European Union herbal monograph on *Origanum majorana* L., herba which is set out in Annex I.

The divergent position is appended to this opinion.

The Norwegian HMPC member agrees with the above-mentioned recommendation of the HMPC.

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

The European Union herbal monograph and assessment report will be published on the European Medicines Agency website.

London, 20 September 2016



**Annex I: European Union herbal monograph
(EMA/HMPC/166517/2015)**

Appendix I: Assessment report (EMA/HMPC/63479/2015)

Appendix II: Divergent position

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

The proposed use of a preparation to be applied to irritated skin around the nostrils is not considered acceptable for use in children from 1 year.

There are concerns that the preparation consists of an extract prepared with white petroleum jelly and the safe use of such a preparation has not been sufficiently demonstrated in young children.

A handwritten signature in black ink, appearing to read 'L. Anderson', with a long horizontal stroke extending to the right.

Linda Anderson, HMPC Member from United Kingdom

London, 20 September 2016