



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

Opinion of the HMPC on a European Union herbal monograph on *Cistus creticus* 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 24 out of 25 votes a European Union herbal monograph on *Cistus creticus* 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 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.

Amsterdam, 19 March 2025.

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Annex I: European Union herbal monograph (EMA/HMPC/150763/2015)

Appendix I: Assessment report (EMA/HMPC/150765/2015)

Appendix II: Divergent position

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

We do not agree with the AR and monograph on *Cistus creticus* L., herba.

Reason:

The divergent opinion is based on the lack of data on the tradition of the described preparation and the related lack of data to substantiate the indication.

There are no data available to meet the requirements of Directive 2001/83/EC (Article 16a(1)(d) in conjunction with Article 16c(1)(c) ["... that the medicinal product in question, or a corresponding product has been in medicinal use throughout a period of at least 30 years preceding the date of the application, including at least 15 years within the Community."]).

There are no products on the European market in which the described preparation has been used for medicinal purposes for 30 years. Bibliographic data cannot be used to meet the requirements of Article 16a(1).

Jacqueline Wiesner, HMPC member from Germany

Amsterdam, 19 March 2025.