



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 *Juniperus communis* L., galbulus (pseudo-fructus)

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 *Juniperus communis* L., galbulus (pseudo-fructus) which is set out in Annex I.

The divergent position are 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 appendix.

The European Union herbal monograph and assessment report will be published on the European Medicines Agency website. They replace those adopted on 12 November 2009.

Amsterdam, 15 March 2023

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Annex I: European Union herbal monograph (EMA/HMPC/241320/2021)

Appendix I: Assessment report (EMA/HMPC/241319/2021)

Appendix II: Divergent position

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

Regarding the EU Herbal monograph for *Juniperus communis* L., galbulus (pseudo-fructus), from a Dutch point of view for indication 1

"Traditional herbal medicinal product used to achieve flushing of the urinary tract as an adjuvant in minor urinary tract complaints. The product is a traditional herbal medicinal product for use in the specified indication exclusively based upon long-standing use", is preferable.

Burt Kroes, HMPC member from Netherlands

Amsterdam, 14 March 2023