

15 January 2020 EMA/HMPC/22334/2020 EMA/HMPC/M/H/0237 Committee on Herbal Medicinal Products (HMPC)

Opinion of the HMPC on a European Union herbal monograph on *Aesculus hippocastanum* L., semen

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 25 out of 26 votes a revised European Union herbal monograph on *Aesculus hippocastanum* L., semen 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 appendix.

The revised European Union herbal monograph and assessment report will be published on the European Medicines Agency website. They replace those adopted on 16 July 2009.

Amsterdam, 15 January 2020



Annex I: European Union herbal monograph (EMA/HMPC/638242/2018)

Appendix I: Assessment report (EMA/HMPC/638244/2018)				
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Appendix II: Divergent position					

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

After discussion and presentation of the new version for Hippocastani semen monograph I am of the opinion that the monograph cannot be fully supported by me without clarification that the correlation factor for specific product, containing Hippocastani semen preparation which have been established on a base of its own analytical tests, have more value than this counted by HMPC (without its analytical verification).

Wojciech Dymowski, HMPC Member from Poland Amsterdam, 15 January 2020