



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/HMPC/332115/2012
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Committee on Herbal Medicinal Products (HMPC)

Opinion of the HMPC on a Community herbal monograph on *Tilia cordata* Miller, *Tilia platyphyllos* Scop., *Tilia x vulgaris* Heyne or their mixtures, flos

Opinion

The HMPC, in accordance with Article 16h(3) of Directive 2001/83/EC, as amended, and as set out in the appended assessment report, establishes by a majority of 26 out of 29 votes a Community herbal monograph on *Tilia cordata* Miller, *Tilia platyphyllos* Scop., *Tilia x vulgaris* Heyne or their mixtures, flos which is set out in Annex I.

The divergent positions 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, to Iceland and Norway, together with its Annex I and appendices.

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

London, 22 May 2012

On behalf of the HMPC

Dr. Werner Knöss, Chair



Annex I: Community herbal monograph (EMA/HMPC/337066/2011)

Appendix I: Assessment report (EMA/HMPC/337067/2011)

Appendix II: Divergent positions

Three members of the HMPC did not agree with the HMPC's opinion on *Tilia cordata* Miller, *Tilia platyphyllos* Scop., *Tilia x vulgaris* Heyne or their mixtures, flos for the following reason:

With regard to *Indication 1*: the data to support use in children below 12 years of age is not sufficient to demonstrate safe use.

With regard to *Indication 2*: the data to support use in adolescents is not sufficient to demonstrate safe use.

22 May 2012