



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

EMA/HMPC/195738/2018  
EMA/HMPC/M/H/0218  
Committee on Herbal Medicinal Products (HMPC)

## Opinion of the HMPC on a European Union herbal monograph on *Vitex agnus-castus* L., 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 18 out of 23 votes a European Union herbal monograph on *Vitex agnus-castus* L., fructus which is set out in Annex I.

The divergent positions are appended to this opinion.

The Norwegian HMPC member does agree 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 European Union herbal monograph and assessment report will be published on the European Medicines Agency website. They replace those adopted on 25 November 2010.

London, 27 March 2018



## **Annex I: European Union herbal monograph (EMA/HMPC/606742/2017)**

## **Appendix I: Assessment report (EMA/HMPC/606741/2017)**

## Appendix II: Divergent positions

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

Finland does not support the proposed monograph for Vitex Agnus-Castus.

The data provided are considered insufficient to support a well-established use indication for Vitex Agnus-Castus as a 'herbal medicinal product for the treatment of premenstrual syndrome'.

The clinical trials are not considered of adequate quality and Vitex Agnus-Castus is not considered to be scientifically proven to have recognised efficacy as required by Article 10a and the Annex of Directive 2001/83/EC, as amended.

Eeva Sofia Leinonen, HMPC Member from Finland

London, 27 March 2018

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

I do not support the proposed monograph for Vitex Agnus-Castus.

The data provided are considered insufficient to support a well-established use indication for Vitex Agnus-Castus as a 'herbal medicinal product for the treatment of premenstrual syndrome'.

The clinical trials are not considered of adequate quality and Vitex Agnus-Castus is not considered to be scientifically proven to have recognised efficacy as required by Article 10a and the Annex of Directive 2001/83/EC, as amended.

Rachel Cox, HMPC Member from Ireland

London, 27 March 2018

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

I do not agree with the HMPC's opinion on Community herbal monograph on *Vitex agnus-castus* L., fructus as the data provided are insufficient to support a well-established use indication as an "herbal medicinal product for the treatment of premenstrual syndrome".

The clinical trials presented are of inadequate quality and *Vitex agnus-castus* L., fructus has not been scientifically proven to have recognized efficacy in accordance with the requirements of Article 10b of Directive 2001/83/EC, as amended.

Alessandro Assisi, HMPC Member from Italy

London, 27 March 2018

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

I do not support the EU herbal monograph for *Vitex agnus-castus*.

The data provided is insufficient to support a well-established use indication for *Vitex agnus-castus* (L.) as an "herbal medicinal product for the treatment of premenstrual syndrome".

The clinical data provided as bibliographical evidence do not support the scientific proof as recognised efficacy in accordance with the requirements of article 10a and Annex 1 of Directive 2001/83/EC as amended.

Furthermore, the indication based on Traditional use, should not include "premenstrual syndrome" but should preferably be: "Traditional herbal medicinal product used for mild complaints related to the premenstrual days".

Emiel Van Galen, HMPC Member from The Netherlands

London, 27 March 2018



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

The United Kingdom does not support the proposed monograph for Vitex Agnus-Castus.

The data provided are considered insufficient to support a well-established use indication for Vitex Agnus-Castus as a 'herbal medicinal product for the treatment of premenstrual syndrome'.

The clinical trials are not considered of adequate quality and Vitex Agnus-Castus is not considered to be scientifically proven to have recognised efficacy as required by Article 10a and the Annex of Directive 2001/83/EC, as amended.

Linda Anderson, HMPC Member from United Kingdom  
London, 27 March 2018