



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

**This document was valid from 25 November 2010 until March 2018.
It is now superseded by a new version adopted by the HMPC on
27 March 2018 and published on the EMA website.**

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 24 out of 31 votes a Community herbal monograph on *Vitex agnus-castus* L., fructus which is set out in Annex I.

The divergent positions are appended to this opinion.

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, 25 November 2010

On behalf of the HMPC

Werner Knöss, Chair



**Annex I: Community herbal monograph
(EMA/HMPC/144006/2009)**

Superseded

Appendix I: Assessment report (EMA/HMPC/144003/2009)

Superseded

Appendix II: Divergent positions

Superseded

Four members of the HMPC did not agree with the HMPC's opinion on Community herbal monograph on *Vitex agnus-castus* L., fructus for the following reason:

We do not support the proposed Community monograph for *Vitex Agnus-Castus* (L.)

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 trials presented are of inadequate quality and *Vitex Agnus-Castus* (L.) has not been scientifically proven to have recognised efficacy in accordance with the requirements of Article 10a and Annex 1 of Directive 2001/83/EC, as amended.

Furthermore, we wish to comment that the indication wording in section 4.1 under Traditional use could be elaborated to explain the symptoms.

25 November 2010

One member of the HMPC did not agree with the HMPC's opinion on Community herbal monograph on *Vitex agnus-castus* L., fructus for the following reason:

No adoption of the proposed indication for *Agni casti fructus* as a traditional herbal medicinal product, "traditional herbal medicinal product for the relief of minor symptoms in the days before menstruation (premenstrual syndrome)" because the core of the indication "for the relief of minor symptoms...." is considered to vague and undetermined. There is no specification of which minor symptoms are meant, which can occur before menstruation and this will impose the risk of misinterpretation by the consumer, taking into account that traditional herbal medicinal products are to be used without the interference of a medical professional.

25 November 2010

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No adoption of the proposed indication for *Agni casti fructus* as a traditional herbal medicinal product, "traditional herbal medicinal product for the relief of minor symptoms in the days before menstruation (premenstrual syndrome)" because the core of the indication "for the relief of minor symptoms...." is considered to vague and undetermined. There is no specification of which minor symptoms are meant, which can occur before menstruation and this will impose the risk of misinterpretation by the consumer, taking into account that traditional herbal medicinal products are to be used without the interference of a medical professional.

25 November 2010

One member of the HMPC did not agree with the HMPC's opinion on Community herbal monograph on *Vitex agnus-castus* L., fructus for the following reason:

The published data could only support a traditional use and the scientific data provided are currently insufficient to recognise *Agnus castus fructus* preparations as well established treatment in premenstrual syndrome. In particular, there are insufficient genotoxicity data to support well established use.

25 November 2010