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Evaluation of Medicines for Human Use

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COMMITTEE ON HERBAL MEDICINAL PRODUCTS (HMPC)

DRAFT

COMMUNITY HERBAL MONOGRAPH ON *VITEX AGNUS-CASTUS* L., FRUCTUS

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KEYWORDS	Herbal medicinal products; HMPC; Community herbal monographs; well-established use; traditional use; *Vitex agnus-castus* L.; Agni casti fructus; agnus castus fruit

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COMMUNITY HERBAL MONOGRAPH ON *VITEX AGNUS-CASTUS* L., FRUCTUS

1. NAME OF THE MEDICINAL PRODUCT

To be specified for the individual finished product.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION[1] [2]

Well-established use	Traditional use
	With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended *Vitex agnus-castus* L., fructus (agnus castus fruit) i) Herbal substance Not applicable ii) Herbal preparations 1) tincture (1:5), extraction solvent: ethanol 58-60% m/m 2) tincture (1:5), extraction solvent: ethanol 70% V/V (manufacture under addition of calcium carbonate) 3) dry extract (7-13:1), extraction solvent: ethanol 60% m/m 4) dry extract (10.0-18.5:1), extraction solvent: ethanol 50-52% m/m

[1] The material complies with the Eur. Ph. monograph (01/2008:2147 corrected 6.2).
[2] The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance

3. PHARMACEUTICAL FORM

Well-established use	Traditional use
	Herbal preparation in solid or liquid dosage forms for oral use. The pharmaceutical form should be described by the European Pharmacopoeia full standard term.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Well-established use	Traditional use
	Traditional herbal medicinal product for the relief of minor symptoms in the days before menstruation (premenstrual syndrome). The product is a traditional herbal medicinal product for use in the specified indication exclusively based upon long-standing use.

4.2. Posology and method of administration

Well-established use	Traditional use
	Posology *Adults* Daily dose: 1) once daily 40 drops 2) once daily 30-40 drops corresponding to approximately 33 mg herbal substance 3) once daily 4 mg dry extract corresponding to 28-52 mg herbal substance 4) once daily 2-3 mg dry extract corresponding to 30-48 mg herbal substance The use in children and adolescents under 18 years of age is not recommended (see section 4.4 'Special warnings and precautions for use'). **Duration of use** If the symptoms persist after a continued use over three cycles, a doctor or a qualified health care practitioner should be consulted.

	Method of administration Oral use.

4.3. Contraindications

Well-established use	Traditional use
	Hypersensitivity to the active substance.

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	Patients who suffer or suffered from an oestrogen-sensitive cancer should consult their doctor before using *Vitex agnus-castus*. Patients who are using dopamine agonists, dopamine antagonists, oestrogens and antioestrogens should consult their doctor before using *Vitex agnus-castus*. (see section 4.5 'Interactions with other medicinal products and other forms of interaction') The use in children and adolescents under 18 years of age has not been established due to lack of adequate data. If the symptoms worsen during the use of the medicinal product or if they do not abate during the first four days of the menstrual cycle or if they recur before cycle day 13, a doctor or a qualified health care practitioner should be consulted. *Vitex agnus-castus* fruits are thought to act on the pituitary-hypothalamic axis and therefore patients with a history of a pituitary disorder should consult with a doctor before using this product. In cases of prolactin secreting tumours of the pituitary gland the intake of *Vitex agnus-castus* fruits can mask symptoms of the tumour. For tinctures extracts containing ethanol, the appropriate labelling for ethanol, taken from the 'Guideline on excipients in the label and package leaflet of medicinal products for human use', must be included.

4.5. Interactions with other medicinal products and other forms of interaction

Well-established use	Traditional use
	Because of the possible dopaminergic and oestrogenic effects of *Vitex agnus-castus* fruits interactions with dopamine agonists, dopamine antagonists, oestrogens and antioestrogens cannot be excluded.

4.6. Pregnancy and lactation

Well-established use	Traditional use
	There is no indication for the use during pregnancy and lactation.

4.7. Effects on ability to drive and use machines

Well-established use	Traditional use
	No studies on the effect on the ability to drive and use machines have been performed.

4.8. Undesirable effects

Well-established use	Traditional use
	Severe allergic reactions with face swelling, dyspnoea and swallowing difficulties. Allergic skin reactions, rash and urticaria, headache, dizziness, gastrointestinal disorders (such as nausea, abdominal pain), acne, menstrual disorders have been reported. The frequency is not known. If other adverse reactions not mentioned above occur, a doctor or a qualified health care practitioner should be consulted.

4.9. Overdose

Well-established use	Traditional use
	No case of overdose has been reported.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Well-established use	Traditional use
	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.

5.2. Pharmacokinetic properties

Well-established use	Traditional use
	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.

5.3. Preclinical safety data

Well-established use	Traditional use
	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended, unless necessary for the safe use of the product. Tests on mutagenicity and carcinogenicity have not been performed. Limited data from reproductive studies suggest that extracts of the fruits influence lactation.

6. PHARMACEUTICAL PARTICULARS

Well-established use	Traditional use
	Not applicable.

7. DATE OF COMPILATION/LAST REVISION

17 September 2009