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Committee on Herbal Medicinal Products (HMPC)

Community herbal monograph on *Vitex agnus-castus* L., fructus

Final

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

BG (bălgarski):	LT (lietuvių kalba):
CS (čeština):	LV (latviešu valoda):
DA (dansk):	MT (malti):
DE (Deutsch):	NL (nederlands):
EL (elliniká):	PL (polski):
EN (English): agnus castus fruit	PT (português):
ES (espanol):	RO (română):
ET (eesti keel):	SK (slovenčina):
FI (suomi):	SL (slovenščina):
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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 marketing authorisation application of Article 10(a) of Directive 2001/83/EC as amended *Vitex agnus-castus* L., fructus (agnus castus fruit) i) Herbal substance Not applicable. ii) Herbal preparations Dry extract (DER 6-12:1) , extraction solvent: ethanol 60% m/m	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 a) Powdered herbal substance b) Tincture (ratio of herbal substance to extraction solvent 1:5), extraction solvent: ethanol 58-60% V/V c) Tincture (ratio of herbal substance to extraction solvent 1:5), extraction solvent: ethanol 70% V/V (manufacture under addition of calcium carbonate) d) Dry extract (DER 7-13:1), extraction solvent: ethanol 60% m/m e) Dry extract (DER 10.0-18.5:1), extraction solvent: ethanol 50-52% m/m

3. Pharmaceutical form

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

1 The material complies with the Ph. Eur. 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.

4. Clinical particulars

4.1. Therapeutic indications

Well-established use	**Traditional use**
Herbal medicinal product for the treatment of premenstrual syndrome.	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: Once daily 20 mg extract equivalent to 180 mg of the 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** To achieve an optimal treatment effect, continued use over three months is recommended. If the symptoms persist after a continued use over three months, a doctor should be consulted. **Method of administration** Oral use.	**Posology** *Adults* Daily dose: a) two times daily 400 mg powdered herbal substance b) once daily 40 drops c) once daily 30-40 drops corresponding to approximately 33 mg herbal substance d) once daily 4 mg dry extract corresponding to 28-52 mg herbal substance e) 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 months, 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.	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 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')	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.	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, a doctor or a pharmacist should be consulted.	If the symptoms worsen during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.
Vitex agnus-castus, fructus is thought to act on the pituitary-hypothalamic axis and therefore patients with a history of a pituitary disorder should consult a doctor before use.	*Vitex agnus-castus*, fructus is thought to act on the pituitary-hypothalamic axis and therefore patients with a history of a pituitary disorder should consult a doctor before use.
In cases of prolactin secreting tumours of the pituitary gland the intake of *Vitex agnus-castus*, fructus can mask symptoms of the tumour.	In cases of prolactin secreting tumours of the pituitary gland the intake of *Vitex agnus-castus*, fructus can mask symptoms of the tumour.
	For tinctures 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*, fructus interactions with dopamine agonists, dopamine antagonists, oestrogens and antioestrogens cannot be excluded.	Because of the possible dopaminergic and oestrogenic effects of *Vitex agnus-castus*, fructus 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. Data from reproductive studies suggest that extracts of *Vitex agnus-castus*, fructus may affect lactation. The use during lactation is not recommended.	There is no indication for the use during pregnancy. Data from reproductive studies suggest that extracts of *Vitex agnus-castus*, fructus may affect lactation. The use during lactation is not recommended.

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.	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 pharmacist should be consulted.	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.	No case of overdose has been reported.

5. Pharmacological properties

5.1. Pharmacodynamic properties

Well-established use	Traditional use
Pharmacotherapeutic group: ATC code: G02CX (Other gynaecologicals) Most preclinical pharmacological data were raised using ethanol or methanol extracts. Inhibitory influences on prolactin release and dopaminergic (dopamine-agonistic) effects were seen by different working groups. There are contradictory results concerning binding to estrogen receptor in general and the preferential binding to β- or α-receptors. Furthermore there are some references concerning β-endorphin-like activity (possibly via μ-opiate receptor binding).	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
No data available.	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**
There are only limited preclinical safety data for *Vitex agnus castus*, fructus or preparations thereof. Tests on mutagenicity and carcinogenicity have not been performed. In two repeat-dose toxicity studies signs of liver toxicity have been observed. In the 26 weeks study, effects were observed at all doses tested. Limited data from reproductive studies suggest that extracts of *Vitex agnus castus*, fructus influence lactation. Adequate tests on reproductive toxicity have not been performed.	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 *Vitex agnus castus*, fructus influence lactation. Adequate tests on reproductive toxicity have not been performed.

6. Pharmaceutical particulars

Well-established use	**Traditional use**
Not applicable.	Not applicable.

7. Date of compilation/last revision

25 November 2010