



NATURAL HEALTH PRODUCT

CHASTE TREE – *VITEX AGNUS-CASTUS*

This monograph is intended to serve as a guide to industry for the preparation of Product Licence Applications (PLAs) and labels for natural health product market authorization. It is not intended to be a comprehensive review of the medicinal ingredient.

Notes

- Text in parentheses is additional optional information which can be included on the PLA and product label at the applicant's discretion.
- The solidus (/) indicates that the terms and/or statements are synonymous. Either term or statement may be selected by the applicant.

Date

March 28, 2024

Proper name(s), Common name(s), Source information

Table 1. Proper name(s), Common name(s), Source information

Proper name(s)	Common name(s)	Source information		
		Source material(s)	Part(s)	Preparation(s)
<i>Vitex agnus-castus</i>	<ul style="list-style-type: none">ChasteberryChastetreeVitex	<i>Vitex agnus-castus</i>	Fruit	Dry

References: Proper name: USDA 2024, Gardner and McGuffin 2013; Common names: USDA 2024, Gardner and McGuffin 2013; Source information: Blumenthal 2000, Mills and Bone 2000.

Route of administration

Oral (WHO 2009; Bradley 2006; Mills and Bone 2000)

Dosage form(s)

This monograph excludes foods or food-like dosage forms as indicated in the Compendium of Monographs Guidance Document.

Acceptable dosage forms for oral use are indicated in the dosage form drop-down list of the web-based Product Licence Application form for Compendial applications.



Use(s) or Purpose(s)

- Used in Herbal Medicine to help relieve premenstrual symptoms (WHO 2009; Bradley 2006; Wichtl 2004; ESCOP 2003; Hoffmann 2003; Blumenthal et al. 2000).
- Used in Herbal Medicine (as a hormone normaliser) to help stabilise menstrual cycle irregularities (WHO 2009; Bradley 2006; Wichtl 2004; ESCOP 2003; Hoffmann 2003; Blumenthal et al. 2000; Mills and Bone 2000).
- Used in Herbal Medicine to help relieve symptoms associated with menopause, such as hot flushes (WHO 2009; Hoffmann 2003).

Note: The above uses can be combined on the product label (e.g. Used in Herbal Medicine as a hormone normaliser to help stabilise menstrual cycle irregularities and relieve premenstrual symptoms).

Dose(s)

Subpopulation(s)

Adults 18 years and older

Quantity(ies)

Methods of preparation: Dry, Powder, Non-Standardized Extracts (Dry extract*, Tincture, Fluid extract, Decoction, Infusion)

30 - 2000 milligrams of dried fruit, per day (WHO 2009; Bradley 2006; ESCOP 2003; Hoffmann 2003; Blumenthal et al. 2000; Mills and Bone 2000).

Notes:

- *Solvents allowed for the method of preparation “Non-standardized extracts (Dry extract)” as part of this monograph are ethanol and/or water only.
- When ‘decoction’ or ‘infusion’ is listed as an acceptable method of preparation, ‘decoction concentrate’ or ‘infusion concentrate’ is also allowed.

Direction(s) for use

No statement required.

Duration(s) of use

Use for at least 3 months to see beneficial effects (Bradley 2006; ESCOP 2003; Hoffmann 2003).



Risk information

Caution(s) and warning(s)

- **Ask a health care practitioner/health care provider/health care professional/doctor/physician if** symptoms persist or worsen.
- **Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if** you are taking hormone-containing medications such as progesterone preparations, oral contraceptives or hormone replacement therapy (Brinker 2010; WHO 2009; Bradley 2006).

Contraindication(s)

Do not use if you are pregnant, breastfeeding or attempting to conceive unless you have consulted with a health care practitioner/health care provider/health care professional/doctor/physician (EMA 2018; Najib et al. 2022; Brinker 2010; WHO 2009; Dugoua et al. 2008; ESCOP 2003; Blumenthal 2000; Mills and Bone 2000).

Known adverse reaction(s)

No statement required.

Non-medicinal ingredients

Must be chosen from the current Natural Health Products Ingredients Database (NHPID) and must meet the limitations outlined in the database.

Storage conditions

Must be established in accordance with the requirements described in the *Natural Health Products Regulations*.

Specifications

- The finished product specifications must be established in accordance with the requirements described in the Natural and Non-prescription Health Products Directorate (NNHPD) Quality of Natural Health Products Guide.
- The medicinal ingredient must comply with the requirements outlined in the NHPID.

EXAMPLE OF PRODUCT FACTS:

Consult the Guidance Document, [Labelling of Natural Health Products](#) for more details.

Product Facts
Medicinal ingredient in each capsule <i>Vitex agnus-castus</i> (Chastetree) – fruit XX mg
Uses <ul style="list-style-type: none"> • Used in Herbal Medicine to help relieve premenstrual symptoms. • Used in Herbal Medicine as a hormone normaliser to help stabilise menstrual cycle irregularities. • Used in Herbal Medicine to help relieve symptoms associated with menopause, such as hot flushes.
Warnings
If applicable¹: Allergens: food allergen, gluten (gluten source), sulphites Contains aspartame
Do not use if you are pregnant, breastfeeding or attempting to conceive unless you have consulted with a health care practitioner.
Ask a health care practitioner before use if you are taking hormone-containing medications such as progesterone preparations, oral contraceptives or hormone replacement therapy.
Ask a health care practitioner if symptoms persist or worsen.
Directions Adults 18 years and older: • Take X capsule(s), X time(s) a day • Use for at least 3 months to see beneficial effects.
Other information (Add storage information)
Non-medicinal ingredients List all NMIs
Questions? (Call) 1-XXX-XXX-XXXX

¹This section can be removed from the table if the product contains no allergen or aspartame.

References cited

Blumenthal M, Goldberg A, Brinkmann J, editors. 2000. Herbal Medicine: Expanded Commission E Monographs. Boston (MA): Integrative Medicine Communications.

Bradley PR, editor. 2006. British Herbal Compendium: A Handbook of Scientific Information on Widely Used Plant Drugs, Volume 2. Bournemouth (GB): British Herbal Medicine Association.

Brinker F. Herb Contraindications and Drug Interactions, 4th edition. Sandy (OR): Eclectic Medical Publications; 2010.

Dugoua JJ, Seely D, Pern D, Koren G, Mills E. Safety and efficacy of chastetree (*Vitex Agnus-Castus*) during pregnancy and lactation. *Can J. Clin Pharmacol* 2008;15(1);e74-e79.

EMA 2018. European Medicines Agency. European Union herbal monograph on *Vitex agnus-castus* L., fructus. London (GB): EMA Committee on Herbal Medicinal Products (HMPC); 27

March 2018. [Accessed 2024 February 29] Available from:
https://www.ema.europa.eu/en/documents/herbal-monograph/final-european-union-herbal-monograph-vitex-agnus-castus-l-fructus-revision-1_en.pdf

ESCOP 2003: European Scientific Cooperative on Phytotherapy Scientific Committee. ESCOP Monographs: The Scientific Foundation for Herbal Medicinal Products, 2nd edition. Exeter (GB): European Scientific Cooperative on Phytotherapy in collaboration with Thieme.

Gardner Z. and McGuffin M. editors. American Herbal Products Association's Botanical Safety Handbook, 2nd edition. American Herbal Products Association. Boca Raton (FL): CRC Press; 2013.

Hoffmann D. 2003. Medical Herbalism: The Science and Practice of Herbal Medicine. Rochester (VT): Healing Arts Press.

Mills S, Bone K. 2000. Principles and Practice of Phytotherapy. Toronto (ON): Churchill Livingstone.

Najib FS, Poordast T, Mahmudi MS, Shiravani Z, Namazi N, Omrani GR. Does Vitex Agnus-Castus L. Have Deleterious Effect on Fertility and Pregnancy Outcome? An Experimental Study on Rats for Prediction of Its Safety. J. Pharmacopuncture 2022;25(2):106-113.

USDA 2024: United States Department of Agriculture, Agricultural Research Service, National Genetic Resources Program. Germplasm Resources Information Network (GRIN) – Global. U.S. National Plant Germplasm System. [Accessed 2024 January 4]. Available from:
<https://npgsweb.ars-grin.gov/gringlobal/taxon/taxonomysearch>

WHO 2009: World Health Organization. WHO Monographs on Selected Medicinal Plants, Volume 4. Geneva (CH): World Health Organization.

Wichtl M, editor. 2004. Herbal Drugs and Phytopharmaceuticals: A Handbook for Practice on a Scientific Basis, 3rd edition. Stuttgart (DE): Medpharm GmbH Scientific Publishers.

References reviewed

Barnes J, Anderson LA, Philipson JD. 2007. Herbal Medicines, 3rd edition. London (GB): The Pharmaceutical Press.

Brinker F. 2001. Herb Contraindications and Drug Interactions, 3rd edition. Sandy (OR): Eclectic Medical Publications.

Ellingwood F. 1998. American Materia Medica, Therapeutics and Pharmacognosy. Sandy (OR): Eclectic Medical Publications; [Reprint of 1919 original].

Felter HW, Lloyd JU. 1983. King's American Dispensatory, Volume 1, 18th edition. Sandy (OR): Eclectic Medical Publications; [Reprint of 1898 original].

Hoffmann D. 2003. Medical Herbalism: The Science and Practice of Herbal Medicine. Rochester (VT): Healing Arts Press.