

5 June 2018
EMA/266692/2018

Agnus castus fruit

Vitex agnus-castus L., fructus

This is a summary of the scientific conclusions reached by the Committee on Herbal Medicinal Products (HMPC) on the medicinal uses of agnus castus fruit. The HMPC conclusions are taken into account by EU Member States when evaluating applications for the licensing of herbal medicines containing agnus castus fruit.

This summary is not intended to provide practical advice on how to use medicines containing agnus castus fruit. For practical information about using agnus castus fruit medicines, patients should read the package leaflet that comes with the medicine or contact their doctor or pharmacist.

What is agnus castus fruit?

Agnus castus fruit is the common name for the fruits of the plant *Vitex agnus-castus* L.

The HMPC conclusions only cover agnus castus fruit preparations that are obtained by drying and powdering the fruit or by putting the plant material in a solvent (such as ethanol) to dissolve compounds and form a liquid extract. The solvent is then evaporated to obtain a dry extract.

Herbal medicines containing these agnus castus fruit preparations are usually available in solid or liquid forms to be taken by mouth.

Agnus castus fruit preparations may also be found in combination with other herbal substances in some herbal medicines. These combinations are not covered in this summary.

What are the HMPC conclusions on its medicinal uses?

The HMPC concluded that one particular dry extract preparation of agnus castus fruit can be used continuously over 3 months for the treatment of premenstrual syndrome (symptoms that occur in the days before a woman's menstrual period).

The HMPC also concluded that, on the basis of their long-standing use, the other agnus castus fruit preparations can be used for relief of minor symptoms in the days before a woman's period.

Agnus castus fruit medicines should only be used in adult women. If the symptoms worsen or continue whilst taking the medicine, a doctor or a qualified healthcare practitioner should be consulted. Detailed instructions on how to take agnus castus fruit medicines and who can use them can be found in the package leaflet that comes with the medicine.



How does agnus castus fruit work as a medicine?

The way agnus castus fruit works is not fully known, but laboratory studies suggest that it may act on the hypothalamus and pituitary gland, hormone secreting areas of the brain, leading to reduced production of the hormone prolactin which is thought to play a role in premenstrual syndrome.

What evidence supports the use of agnus castus fruit medicines?

The HMPC conclusions on the use of the agnus castus fruit dry extract for the treatment of premenstrual syndrome are based on 'well-established use'. This means that there are bibliographic data providing scientific evidence of effectiveness and safety when used in this way, covering a period of at least 10 years in the EU.

In its assessment, the HMPC considered one study in 178 women where this dry extract of agnus castus fruit was compared with placebo (a dummy treatment). Results showed that women with premenstrual syndrome treated with the agnus castus extract had improvements in menstrual symptoms such as irritability, mood alteration, anger, headache and breast fullness.

The HMPC conclusions on the use of the other agnus castus preparations for relief of minor symptoms in the days before a period are based on their 'traditional use'. This means that, although there is insufficient evidence from clinical trials, the effectiveness of these herbal medicines is plausible and there is evidence that they have been used safely in this way for at least 30 years (including at least 15 years within the EU). Moreover, the intended use does not require medical supervision.

In its assessment, the HMPC also considered clinical studies on premenstrual syndrome with the other agnus castus preparations. Although a possible effect in relieving symptoms was observed, firm conclusions could not be drawn because of poor study design. Therefore, the HMPC conclusions on the use of these preparations are based on their long-standing use.

For detailed information on the studies assessed by the HMPC, see the HMPC assessment report.

What are the risks associated with agnus castus fruit medicines?

Side effects with agnus castus fruit medicines include severe allergic reactions with face swelling, difficulty breathing and swallowing, skin effects (such as rash and acne), headache and dizziness, stomach and gut effects (such as nausea and belly pain) and menstrual disorders. The frequency of these side effects is unknown.

Further information on the risks associated with these agnus castus fruit medicines, including the appropriate precautions for their safe use, can be found in the monograph under the tab 'All documents' on the Agency's website: ema.europa.eu/Find medicine/Herbal medicines for human use.

How are agnus castus fruit medicines approved in the EU?

Any applications for the licensing of medicines containing agnus castus fruit have to be submitted to the national authorities responsible for medicinal products, which will assess the application for the herbal medicine and take into account the scientific conclusions of the HMPC.

Information on the use and licensing of agnus castus fruit medicines in EU Member States should be obtained from the relevant national authorities.

Other information about agnus castus fruit medicines

Further information on the HMPC assessment of agnus castus fruit medicines, including details of the Committee's conclusions, can be found under the tab 'All documents' on the Agency's website: ema.europa.eu/Find medicine/Herbal medicines for human use. For more information about treatment with agnus castus fruit medicines, read the package leaflet that comes with the medicine or contact your doctor or pharmacist.