# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Agnus castus oral drops

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose (15-20 drops) contains 407 – 542 mg of tincture from Agnus castus fruits (*Vitex agnus-castus* L.) (1:10). Extraction solvent: ethanol 69.5% v/v.

1 ml of oral drops contains 895 mg of tincture (equivalent to 33 drops).

Excipients with known effect:

Each dose (15 -20 drops) contains approximately 252 – 336 mg of ethanol (alcohol).

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Oral drops, solution.
Clear, yellow-brown liquid.

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic Indications

A traditional herbal medicinal product for the relief of minor symptoms of premenstrual syndrome, exclusively based upon long-standing use.

This product is indicated for use in women over 18 years of age.

### 4.2 Posology and method of administration

**Posology**
Women experiencing minor premenstrual symptoms: Take 15-20 drops in a little water twice daily.

As treatment effects may not be apparent immediately, the product may need to be taken up to 3 months continuously.

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 symptoms worsen during use or do not improve after a continued use over 3 months, a qualified healthcare professional e.g. a doctor or pharmacist should be consulted.

**Method of administration**

For oral use only.

**4.3 Contraindications**

Do not use in cases of known hypersensitivity to Agnus castus fruit or to any of the excipients listed in section 6.1.

Pregnancy and lactation (see section 4.6)

Current pituitary disorder.

**4.4 Special warnings and precautions for use**

Do not exceed stated dose.

Patients who suffer or suffered from an oestrogen-sensitive cancer should consult their doctor before using Agnus castus.

Patients who are using dopamine agonists, dopamine antagonists, oestrogens and antioestrogens should consult their doctor before using 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 symptoms worsen during use or do not improve after a continued use over 3 months a qualified healthcare professional, e.g. a doctor or pharmacist should be consulted.

Agnus castus fruits are thought to act on the pituitary-hypothalamic axis and therefore patients with a history of pituitary disorder should consult a doctor before using this product. In cases of prolactin secreting tumours of the pituitary gland the intake of Agnus castus fruits can mask symptoms of the tumour.

This product contains 69.5 V/V% ethanol (alcohol).

Each dose (15-20 drops) contains approximately 252 – 336 mg of ethanol (alcohol) equivalent to 6.3 – 8.4 ml beer or 2.58 - 3.5 ml wine.

Harmful for those suffering from alcoholism. To be taken into account in pregnant, or breast-feeding women, children and high-risk groups such as patients with liver disease or epilepsy.

**4.5 Interaction with other medicinal products and other forms of interactions**

Because of the possible dopaminergic and oestrogenic effects of Agnus castus fruits, interactions with dopamine agonists, dopamine antagonists, oestrogens and anti-oestrogens cannot be excluded.

Contains alcohol and should be avoided in patients taking other medicines known to interact with alcohol (e.g. metronidazole).

**4.6 Fertility, pregnancy and lactation**

The indication excludes the use during pregnancy.

Data from reproductive studies suggest that extracts of Agnus castus fruits may affect lactation. Therefore use during lactation should be avoided.

Due to the potential for Agnus castus fruits to have hormone-like actions, use should be avoided by women who are trying to get pregnant.

Studies on fertility have not been performed.

**4.7 Effects on ability to drive and use machines**

No studies on the effect on the ability to drive and use machines have been performed.
This product contains alcohol (See Section 4.4 for details of alcohol content).

**4.8 Undesirable effects**

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 qualified healthcare professional e.g. a doctor or pharmacist should be consulted.

**Reporting of suspected adverse reactions**

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie

**4.9 Overdose**

Overdose of this product may result in alcohol intoxication: the amount of alcohol in a full bottle (27.75 g in 50 ml equivalent to 1 or 2 small glasses of wine, respectively) may result in intoxication and should be treated accordingly.

In the event of an overdose, patients are advised to contact a doctor, pharmacist or healthcare professional.

**5 PHARMACOLOGICAL PROPERTIES**

**5.1 Pharmacodynamic properties**

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

**5.2 Pharmacokinetic properties**

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

**5.3 Preclinical safety data**

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.

An Ames test conducted with Agnus castus extract showed no mutagenic effects. Tests on carcinogenicity have not been performed.

Limited data from reproductive studies suggest that extracts of Agnus castus fruits influence lactation.

Adequate tests on reproductive toxicity have not been performed.

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

**From tincture:**
Ethanol
Purified water

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf life

4 years.

### 6.4 Special precautions for storage

This medicinal product does not require any special storage conditions

### 6.5 Nature and contents of container

Brown glass dropper bottles (Type III glass Ph.Eur.) with a tamper-proof screw cap (cap (polypropylene), tamper ring (high density polyethylene)) fitted with a drop dispenser (low density polyethylene).

Pack size 50 ml

Brown glass bottles (Type III glass Ph.Eur.) with a child-resistant closure (cap (high density polyethylene), child-resistant closure (high density polyethylene)) fitted with a drop dispenser (low density polyethylene).

Pack size 50 ml

Not all pack sizes may be marketed.

### 6.6 Special precautions for disposal and other handling

No special requirements

## 7 REGISTRATION HOLDER

A. Vogel Ireland Limited
48 Upper Drumcondra Road
Dublin 9
Ireland

## 8 REGISTRATION NUMBER(S)

TR2309/017/001

## 9 DATE OF FIRST REGISTRATION/RENEWAL OF THE REGISTRATION

Date of first authorisation: 12th December 2014

## 10 DATE OF REVISION OF THE TEXT

November 2018