Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Natures Aid Premeeze Agnus Castus hard capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each hard capsule contains 400 mg of *Vitex agnus-castus* L., fructus (Agnus castus fruit).
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Hard capsules (capsules)
Clear size 0 hard capsules with brown powder fill.

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.
Natures Aid Premeeze Agnus Castus Capsules are indicated for use in women over 18 years of age.

4.2 Posology and method of administration

Posology
For women experiencing premenstrual symptoms: Take one capsule twice a day (morning and night) swallowed with water.
Maximum dose: Two capsules daily

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

The use in children and adolescents under 18 years of age is not recommended (see section 4.4).

Method of administration
For oral use only.
Duration of use
If symptoms persist, worsen, or do not improve after 3 months use, a qualified healthcare professional e.g. a doctor or pharmacist should be consulted.

4.3 Contraindications

Hypersensitivity to Agnus Castus fruit or to any of the excipients listed in section 6.1.
Current pituitary disorder.
Pregnancy or lactation (see section 4.6).

4.4 Special warnings and precautions for use

Do not exceed the stated dose.
Patients who suffer from or suffered from an oestrogen-sensitive cancer should consult their doctor before using Natures Aid Premeeze Agnus Castus Capsules.
Patients who are using dopamine agonists, oestrogens and antioestrogens should consult their doctor before using Natures Aid Premeeze Agnus Castus Capsules (see section 4.5).
The use in children and adolescents under 18 years of age has not been established due to lack of adequate data.
If the symptoms persist, or worsen during the use of the product, or do not improve after 3 months of using the product, a qualified healthcare professional e.g. a doctor or pharmacist 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.

4.5 Interaction with other medicinal products and other forms of interaction

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 Fertility, pregnancy and lactation

Pregnancy
The indication excludes the use in pregnancy (see section 4.3).
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. Animal studies are insufficient with respect to reproductive toxicity (see section 5.3).
Breast- feeding
It is unknown whether agnus castus fruit or its metabolites are excreted in human milk. Data from reproductive studies suggest that agnus castus fruit may affect lactation. A risk to the suckling child cannot be excluded. Therefore, use during lactation should be avoided (See section 4.3).
Fertility
No studies on the effect on fertility have 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.

4.8 Undesirable effects

Immune system disorders (severe allergic reactions with face swelling, dyspnoea and swallowing difficulties), skin and subcutaneous tissue disorders (allergic skin reactions such as rash and urticaria, acne), nervous system disorders (headache, dizziness), gastrointestinal disorders (nausea, abdominal pain), and reproductive system disorders (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 of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the:
HPRA Pharmacovigilance
Website: www.hpra.ie

4.9 Overdose

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

Agnes Castus powder did not demonstrate genotoxic potential in a standard Ames test.
Tests on carcinogenicity and adequate tests on reproductive toxicity have not been performed.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hypromellose (capsule shell)

6.2 Incompatibilities

Not applicable

6.3 Shelf life

24 Months

6.4 Special precautions for storage

Store below 25^0C.
Store in the original container.

6.5 Nature and contents of container

Ph Eur type III glass bottles with polypropylene screw cap incorporating an induction heat seal liner. Printed outer carton containing Patient Information Leaflet.
Pack sizes: 30, 60, 90, 120 hard capsules. Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7 REGISTRATION HOLDER

Clonmel Healthcare Ltd
Waterford Road
Clonmel, Co. Tipperary
E91 D768
Ireland

8 REGISTRATION NUMBER(S)

TR0126/312/001

9 DATE OF FIRST REGISTRATION/RENEWAL OF THE REGISTRATION

Date of first registration: 8th January 2021
Date of last renewal: 02nd May 2025

10 DATE OF REVISION OF THE TEXT

May 2025