# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Nature's Bounty Agnus Castus PMS Relief Tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 3.9 mg of extract (as dry extract) from Agnus Castus fruit (*Vitex agnus castus* L.) equivalent to 23.4 – 31.2 mg of Agnus Castus fruit.
Extraction solvent: Ethanol 75%v/v.

For a full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Film-coated tablet.
Clear film coated, speckled brown round-shaped tablet, plain on both sides.

## 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.

### 4.2 Posology and method of administration

For oral short-term use only.

**Adults**
**Women experiencing minor premenstrual symptoms**:
Take 1 tablet daily. Swallow the whole tablet with water. The tablet should be taken at the same time of the day (morning or evening).

Do not exceed the stated dose

**Duration of use:**
If symptoms worsen during the use of this product or do not improve after a continued use over three months, a qualified Healthcare Professional e.g. a doctor or pharmacist should be consulted.

Not for use in children under 18 years (see section 4.4 Special warning and precautions for use).

### 4.3 Contraindications

- Hypersensitivity to Agnus Castus or any of the excipients
- Pregnancy and lactation (see section 4.6)
- Current pituitary disorder

### 4.4 Special warnings and precautions for use

- Patients who suffer or who have suffered from an oestrogen-sensitive cancer should consult their doctor before using Vitex agnus-castus

- In cases of prolactin secreting tumours of the pituitary gland, the intake of agnus-castus, can mask symptoms of the tumor.

- Agnus Castus is 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.

- Patients who are using dopamine agonists, dopamine antagonists, oestrogens and antioestrogens should consult their doctor before using Vitex agnuscastus. (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 the symptoms worsen during the use of the medicinal product, a qualified healthcare professional e.g. a doctor or pharmacist should be consulted.

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

Because of the possible dopaminergic and oestrogenic effects of *Vitex agnus-castu,* fructus interactions with dopamine agonists, dopamine antagonists, oestrogens and antioestrogens cannot be excluded.

**4.6 Fertility, pregnancy and lactation**

- The indication excludes the use during pregnancy.

- Data from reproductive studies suggest that extracts of Vitex agnus-castus, fructus may affect lactation. Therefore use during lactation should be avoided.

- Due to the potential for Vitex agnus-castus 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.

**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**

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**

In vitro tests for detection of gene mutation (Ames test) with Agnus Castus fruit did not demonstrate genotoxic activity. Tests on reproductive toxicity and carcinogenicity have not been performed

**6 PHARMACEUTICAL PARTICULARS**

**6.1 List of excipients**

Tablet Core
Maltodextrin
Silica colloidal anhydrous
Microcrystalline cellulose
Croscarmellose sodium
Magnesium stearate
Silica colloidal hydrated

Tablet Coating
Hypromellose
Glycerol

**6.2 Incompatibilities**

Not applicable.

**6.3 Shelf life**

3 years

**6.4 Special precautions for storage**

Do not store above 25°C.
Store in the original packaging. Keep the bottle tightly closed in order to protect from light and moisture.

**6.5 Nature and contents of container**

Green polyethylene terephthalate (PET) bottles with a polypropylene cap and an inner seal liner made up of polyester, polymer adhesive layer, polyolefin foam and aluminium foil.

Bottles contain 30 or 60 tablets.

Not all pack sizes may be marketed.

**6.6 Special precautions for disposal**

No special requirements.

**7 REGISTRATION HOLDER**

Holland & Barrett Limited
Cedar Drive
Dublin Airport Logistics Park
Saint Margarets
Co Dublin

K67 E0C5
Ireland

**8 REGISTRATION NUMBER(S)**

TR23157/012/001

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

Date of first registration: 30th May 2014

**10 DATE OF REVISION OF THE TEXT**

February 2021