

## Package leaflet: Information for the user

### < Nature's Bounty Agnus Castus PMS Relief Tablets > < Agnus Castus fruit extract >

#### Important Notes

**Please read all of this leaflet carefully before you use this traditional herbal medicine because it contains important information for you**

- Always take this traditional herbal medicine exactly as described in this leaflet or as your doctor or pharmacist has told you
- Keep this leaflet. You may need to read it again
- Ask a healthcare professional e.g. a doctor or pharmacist if you need more information or advice
- Please tell a doctor or pharmacist if you suffer from side effects not listed in this leaflet and/or if any of the side effects become serious
- Please tell a doctor or pharmacist if your symptoms worsen during use of this product or do not improve after continued use over 3 months

#### What is in this leaflet

1. What this traditional herbal medicine is and what it is used for
2. What you need to know before you take this traditional herbal medicine
3. How to take this traditional herbal medicine
4. Possible side effects
5. How to store this traditional herbal medicine
6. Contents of the pack and other information

#### 1. What this traditional herbal medicine is and what it is used for

This product contains Agnus Castus fruit extract. It is a traditional herbal medicinal product used for the relief of minor symptoms of premenstrual syndrome, exclusively based upon long-standing use

#### 2. What you need to know before you take this traditional herbal medicine

Do not take this traditional herbal medicine if you are:

- Under 18 years of age
- Pregnant or breastfeeding
- Trying to become pregnant
- Allergic to any of the ingredients in this traditional herbal medicine

(see section 6 of this leaflet)

- Currently suffering from a pituitary disorder

**Consult a doctor before taking this traditional herbal medicine** if you:

- Suffer from or have suffered from an oestrogen sensitive cancer
- Had a pituitary disorder in the past
- Are taking dopamine agonists, dopamine antagonists, oestrogens or antioestrogens

If you are taking a dopamine-receptor antagonist or agonist type drug, there is a theoretical risk that this product may affect the way they work.

**Warnings and Precautions:** Talk to your doctor or pharmacist before taking this traditional herbal medicine if you are currently suffering from a pituitary disorder.

**Children and adolescents:** Do not give this traditional herbal medicine to children or adolescents under the age of 18 years as it is not known if it is safe to do so.

**Other medicines and Nature's Bounty Castus PMS Relief Tablets including traditional herbal medicines:** Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including herbal medicines such as this one, or other medicines that didn't require a prescription.

**Pregnancy, breastfeeding and fertility:** Do not take this traditional herbal medicine if you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby.

### **3. How to take this traditional herbal medicine**

Always take this traditional herbal medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

**For oral short-term use only.**

**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). Some women may need to take this medicine for up to 3 months for maximum benefit to occur.

The maximum dose is 1 tablet per day.

**Do not exceed the stated dose.**

If you take more of this traditional herbal medicine than you should (overdose): Speak to a doctor or pharmacist immediately and take this leaflet and bottle with you.

**If you forget to take this medicine: Do not take a double dose to make up for the missed dose(s).**

Continue to take your usual dose at the usual time. It does not matter if you have missed a dose. If you have further questions on the use of this traditional herbal medicine, please ask a qualified healthcare practitioner e.g. a doctor or pharmacist.

**Duration of use:** If these 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 a pharmacist should be consulted. More information on back panel.

### **4. Possible side effects**

Like all medicines, Agnus Castus can have side effects, although not everybody gets them. The frequency is unknown.

Possible side effects are:

- Gastrointestinal disorders (nausea, abdominal pain)
- Allergic skin reactions (rash, urticaria)
- Headache
- Dizziness
- Acne
- Menstrual disorders
- Severe allergic reactions such as face swelling, shortness of breath and swallowing difficulties

### **Reporting of side effects**

If you get any side effects, talk to your qualified healthcare professional such as doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance

Website: [www.hpra.ie](http://www.hpra.ie)

By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store this traditional herbal medicine**

- Keep this traditional herbal medicine out of sight and reach of children.
- Keep this traditional herbal medicine in the bottle until it is time to take it.
- Do not use this traditional herbal medicine after the expiry date which is stated on the carton and bottle label after 'EXP'. The expiry date refers to the last day of that month.
- Do not store above 25°C.
- Keep the bottle tightly closed in order to protect from light and moisture
- Store in original packaging

## **6. Contents of the pack and other information**

### **What this traditional herbal medicine contains:**

Each film-coated tablet contains 3.9 mg of extract (as dry extract) from *Vitex agnus castus* L., fructus (Agnus Castus fruit) equivalent to 23.4 – 31.2 mg of Agnus Castus fruit.

Extraction solvent: Ethanol 75 %v/v.

### **This traditional herbal medicine also contains the following inactive ingredients (excipients):**

Tablet core: Microcrystalline cellulose, Croscarmellose sodium, Magnesium stearate, Silica colloidal hydrated.

**Tablet coating:** Hypromellose, Glycerol.

Excipients in the extract: Maltodextrin, Silica colloidal anhydrous.

### **What Nature's Bounty Agnus Castus PMS Relief Tablets look like and contents of the pack:**

Each bottle contains 30 or 60 clear, film-coated, speckled, brown, round shaped tablets, plain on both sides.

**Traditional Registration Holder**

TR23157/012/001

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