

Package Leaflet: Information for the user

Agnus castus oral drops Agnus castus tincture

Read all of this leaflet carefully before you start taking this product because it contains important information for you.

Always take this product exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 3 months.

What is in this leaflet

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

1. WHAT AGNUS CASTUS IS AND WHAT IT IS USED FOR

Agnus castus is a traditional herbal medicinal product containing the extract of Agnus castus fruit.

It is used to relieve the minor symptoms of premenstrual syndrome-
This is exclusively based on long-standing use.

Agnus castus is for use in women over 18 years of age.

Premenstrual syndrome (PMS) consists of the symptoms that can occur in the two weeks before a monthly period. It is also known as premenstrual tension (PMT). Symptoms can be both physical and emotional and can include irritability, mood swings, breast tenderness, bloating and menstrual cramps.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE AGNUS CASTUS

Do not take Agnus castus

- If you are allergic to any of the ingredients of this product (listed in section 6).
- If you have a pituitary disorder.
- If you are pregnant, trying to become pregnant or breast-feeding.

Warnings and precautions

- Talk to your doctor **before** taking this product if:
 - You suffer from or have suffered from an oestrogen-sensitive cancer
 - You have suffered from a pituitary disorder
- Talk to your doctor or pharmacist if your symptoms worsen or do not improve after taking this product for 3 months,

Children and adolescents

- Do not give this product to children or adolescents under 18 years of age.

Other medicines and Agnus castus

- Do not take this product if you are already taking another medicine which is affected by alcohol.
- Talk to your doctor **before** taking this product if you are taking any of the following medicines:
 - Dopamine agonists
 - Dopamine antagonists
 - Oestrogens
 - Antioestrogens
- If you are speaking to your doctor, pharmacist or nurse always remember to tell them about any medicines you are taking, including herbal remedies such as Agnus castus.

Driving and using machines

- This product contains alcohol (see below for alcohol content). Overdose of the product may result in alcohol intoxication.

Agnus castus contains alcohol

- This medicine contains approximately 277 – 369 mg of alcohol (ethanol) in each 15 – 20 drops, respectively.
- The amount in 15 – 20 drops of this medicine is equivalent to less than 7 – 9 ml beer (around two teaspoons) or 3 – 4 ml wine (less than a teaspoon).
- The small amount of alcohol in this medicine will not have any noticeable effects.

3. HOW TO TAKE AGNUS CASTUS

Always take this product exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

Recommended dose

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

The effects of this product may not be felt immediately. For best results you may need to take this product for up to 3 months.

For oral use only. Do not take more than the recommended dose.

If you take more Agnus castus than you should

- If you take too much and feel ill, talk to your doctor.
- Overdose of this product may result in alcohol intoxication.

If you forget to take Agnus castus

- Do not worry about the missed dose. Take the next dose as usual.
- Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this product ask your doctor, pharmacist or nurse.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this product can cause side effects, although not everybody gets them.

Side effects

Allergic reactions

- Swelling of the face, breathlessness and difficulty swallowing
- Stop taking the product immediately if these occur. Seek medical advice and take this leaflet with you.

Skin reactions

- Rash
- Red, itchy spots (urticaria)

Stop taking the product if these occur.

Other reactions

- Headache
- Dizziness
- Digestive upsets such as feeling sick or stomach pain
- Acne
- Menstrual disorders

These are often short-lived and should go away by themselves. However if they persist, talk to your doctor, pharmacist or nurse.

The frequency of these side effects is not known. This means it is not known how often these reactions occur as there have not been enough reports to allow this information to be calculated.

Reporting of side effects

- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any side effects not listed in this leaflet.
- You can also report side effects directly 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
- By reporting any side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE AGNUS CASTUS

- Keep this product out of the sight and reach of children.
- Do not use this product after the expiry date which is stated on the label and carton. The expiry date refers to the last day of that month.
- This product does not require any special storage conditions.
- Do not use this product if you notice a change in appearance. It should be a clear liquid that is yellow-brown in colour.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND FURTHER INFORMATION

What Agnus castus contains

One dose (15-20 drops) contains 448-597 mg of tincture from *Vitex agnus-castus* L., fructus (Agnus castus fruit) (1:10). Extraction solvent: Ethanol 69.5% V/V.

1 ml of Agnus castus oral drops is equivalent to 30 drops.

The other ingredients used for the liquid are ethanol and water.

What Agnus castus looks like and contents of the pack

Agnus castus oral drops is a clear liquid that is yellow-brown in colour. Agnus castus is available in 50 ml amber glass bottles.

Traditional Registration Holder

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What is Agnus castus?

Agnus castus is a flowering plant which is native to the Mediterranean. It is the extract of the fruit which is used to make Agnus castus drops.

You should also know

A.Vogel Ireland runs a helpline by phone and email which can provide you with further information.

E-mail: enquiries@avogel.ie

Phone: 0818 930 070

You can get a larger print or audio version of this leaflet. Call this number: 0818 930 070