

SUMMARY OF PRODUCT CHARACTERISTICS

PREMHERB

1 NAME OF THE MEDICINAL PRODUCT

PremHerb Film-coated Tablets
Femlieve Film-coated Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains: 4.0 mg of extract (as dry extract) from *Agnus castus* fruit (*Vitex agnus castus* L.) (7-13:1)(equivalent to 28-52 mg of *Agnus castus*).

Extraction solvent: Ethanol 60% m/m.

Excipients: 1 film-coated tablet contains 124 mg of lactose monohydrate and 36 mg of liquid glucose.

For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Film-coated tablet.
Salmon pink, round, convex, scored tablet.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

A traditional herbal medicinal product that has been used to help relieve the symptoms associated with premenstrual syndrome, based on traditional use only.

4.2 Posology and method of administration

For oral use only.

For women experiencing premenstrual symptoms, take 1 tablet daily. Tablets should be taken at the same time of day if possible (morning or evening) and swallowed whole with plenty of liquid. Some individuals may need to take PremHerb for up to 3 months for maximum benefit to occur.

Women suffering from a current pituitary disorder should not take PremHerb.

Not for children and adolescents under 18 years.

4.3 *Contraindications*

Hypersensitivity to dry extract of *Agnus castus* fruit, or any of the other ingredients in the drug.

This product is not recommended for use in children, adolescents under 18 years or for patients with a current pituitary disorder.

4.4 *Special warnings and precautions for use*

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.

This product contains glucose:
1 film-coated tablet contains max. 36 mg

This product contains lactose:
1 film-coated tablet contains max. 124 mg lactose.

Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

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

There are no published data available on drug interactions with extracts of *Agnus castus*.

Animal experiments have shown that that the drug has a dopaminergic effect and so, theoretically, there could be a reduction in the effectiveness of dopamine-receptor antagonists, and/or a potentiation of dopamine-receptor agonists.

4.6 *Pregnancy and lactation*

The safety of the product during pregnancy and lactation has not been established, therefore it should be avoided during pregnancy or while breastfeeding. Additionally, because of the potential for the product to have hormone-like actions the product should also be avoided by women who are trying to become pregnant.

4.7 *Effects on ability to drive and use machines*

None known.

4.8 *Undesirable effects*

Mild and reversible, transient side-effects are associated with Agnus castus use. Postmarketing surveillance studies suggest that the approximate incidence of adverse effects is between 1.9 - 5 %. Most frequently these are:

Nausea
Stomach disturbances
Headache
Diarrhoea
Allergic skin reactions.

If there are signs of an allergic reaction the product should be withdrawn.

4.9 *Overdose*

In the event of an overdose, patients are advised to contact a doctor, pharmacist or healthcare professional. A small overdose (up to 8 tablets) may not cause any symptoms. In the event of a large overdose (more than 8 tablets), advice should be sought from a doctor.

Management of an overdose should include appropriate symptomatic and supportive treatment as warranted by the clinical situation.

5 PHARMACOLOGICAL PROPERTIES

5.1 *Pharmacodynamic properties*

No pharmacodynamic studies have been undertaken with Premherb and the pharmacodynamic properties are unknown.

5.2 *Pharmacokinetic properties*

Pharmacokinetic studies have not been conducted with Premherb or its active constituents.

5.3 *Preclinical safety data*

The non-clinical toxicology data available are limited. Tests on reproductive toxicity, genotoxicity and carcinogenicity have not been performed.

6 PHARMACEUTICAL PARTICULARS

6.1 *List of excipients*

Tablet core:

Liquid glucose (dry substance)
Silica, colloidal anhydrous
Lactose monohydrate

Magnesium stearate
Maize starch
Cellulose, microcrystalline
Sodium starch glycolate (Type A)
Film coating:
Lactose monohydrate
Hypromellose
Macrogol 4000
Titanium dioxide E171
Iron(III)-oxide E172 (==red iron oxide)

6.2 *Incompatibilities*

Not applicable.

6.3 *Shelf life*

The shelf life is 3 years

6.4 *Special precautions for storage*

This product does not require any special storage instructions

6.5 *Nature and contents of container*

Original packages containing 30 or 60 film-coated tablets

PremHerb[®] film-coated tablets are packed in PVC/ PVDC aluminium blisters and inserted into a carton.

6.6 *Special precautions for disposal*

No special requirements

7 REGISTRATION HOLDER

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8 REGISTRATION NUMBER

THR 23056/0002

9 DATE OF FIRST REGISTRATION

16th October 2007

10. DATE OF REVISION OF TEXT