Prefemin -DL-April2020-01

Summary of product characteristics

1 NAME OF THE MEDICINAL PRODUCT

Prefemin®

2 QUALITATIVE UND QUANTITATIVE COMPOSITION

1 film coated tablet contains:

20 mg Agni casti fructus (agnus castus) dry extract, Native (DER 6-12 : 1).

Excipient with known effect

40 mg lactose monohydrate

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

film coated tablet

round, white, biconvex film coated tablet

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the treatment of PMS (premenstrual syndrome) complaints recurring monthly prior to menstruation, in adults.

4.2 Posology and method administration

Posology

Adult women

1 film coated tablet daily in the morning

Children and adolescents

Prefemin is not indicated for children and adolescents below 18 years of age due to lack of adequate data.

Method of administration

Oral

The film coated tablet is taken unchewed with a sufficient amount of liquid.

The film coated tablet should preferably be taken at the same time each day.

Duration of use

To achieve an optimal treatment effect, continued use over three months is recommended.

If the symptoms worsen or no improvement occurs after three months, a physician should be consulted.

4.3 Contraindication

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Patients who suffer or have suffered from an oestrogen-sensitive cancer should consult their physician before using Prefemin.

Patients who are using dopamine agonists, dopamine antagonists, oestrogens or antioestrogens should consult their physician before using Prefemin (see section 4.5).

Agnus castus fruit extracts are thought to act on the pituitary-hypothalamic axis. Therefore, patients with a history of a pituitary disorder should consult a physician about the intake of this medicinal product.

In cases of prolactin secreting tumours of the pituitary gland the intake of Agnus castus extracts can mask symptoms of the tumour.

The film coated tablets contain lactose monohydrate.

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

4.5 Interaction with other medicinal products and other forms of interaction

Because of the possible dopaminergic and oestrogenic effects of Agnus castus extracts, interactions with dopamine agonists, dopamine antagonists, oestrogens and antioestrogens cannot be excluded.

4.6 Fertility, pregnancy and lactation

There is no indication for the use during pregnancy.

Data from reproductive studies suggest that Agnus castus extract may affect lactation. The use during lactation is not recommended.

There are no data on the effect on fertility.

4.7 Effects on ability to drive and use machines

No studies on the influence on the ability to drive and use machines have been performed.

4.8 Undesirable effects

The frequency of undesirable effects is unknown.

Immune system disorders

Severe allergic reactions with face swelling, dyspnoea and swallowing difficulties

Skin and subcutaneous tissue disorders

(Allergic) skin reactions (rash, urticaria), acne

Nervous system disorders

Headache, dizziness

Gastrointestinal disorders

Gastrointestinal disorders (such as nausea, abdominal pain)

Reproductive system and breast disorders

Menstrual disorders

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.

Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form

http://sideeffects.health.gov.il

4.9 Overdose

Cases of overdose are not known.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: other gynecologicals

ATC code: G02CX

There is evidence that Agnus castus extracts inhibit the prolactin release in vitro. The inhibitory influence on prolactin release and the dopaminagonistic effect have been shown in various tests.

There are contradictory results regarding the binding of agnus-castus extracts to the oestrogen receptors, and it is unclear whether agnus-castus extracts have a higher binding affinity to β- or α-receptors. There are some references concerning the β-endorphin-like activity (possibly via the μ-opiate receptor binding).

Clinical efficacy

170 women diagnosed with PMS were treated with in a randomised, double-blind, study over three menstrual cycles, either with Agnus castus dry extract Ze 440 or placebo. The women treated with Agnus castus dry extract Ze 440 had significantly reduced PMS (irritability, mood swings, anger and headache) compared to those treated with placebo.

5.2 Pharmacokinetic properties

Data on pharmacokinetics are not available.

5.3 Preclinical safety data

Studies on acute, sub-acute and chronic toxicity as well as standard genotoxicity studies revealed no particular risk for humans.

Limited data from reproductive studies suggest that Agnus castus extracts influence lactation.

Adequate tests on reproductive toxicity and carcinogenicity have not been performed.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Microcrystalline cellulose, Lactose monohydrate, Silica colloidal anhydrous, Hypromellose, Titanium dioxide, Magnesium stearate, Macrogol 400, Propylene glycol, Macrogol 20,000.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The expiry date of the product is indicated on the packaging materials.

6.4 Special precautions for storage

Store below 25 °C.

6.5 Nature and contents of container

PVC/PVdC aluminium blisters with 30 or 90 film coated tablets.
It is possible, that not all pack sizes are marketed.

7 MANUFACTURER

MAX Zeller Sohne AG, Romanshorn, Switzerland

8 REGISTRATION HOLDER

Rafa Laboratories Ltd., P.O.Box 405, Jerusalem 9100301

Drug registration number: 164-38-35417

Approved in April 2020