Patient Leaflet According to the Pharmacists' Regulations (Preparations) - 1986
This medicine is sold without a doctor's prescription

Prefemin®
Film-coated tablets

Active ingredient:
Each tablet of Prefemin contains: 20 mg of Agnus castus dry extract (Agni casti fructus).
For a list of other ingredients, please see Section 6.
See also 'Important information on some of the medicine's ingredients in Section 2.

Read the entire leaflet carefully before using the medicine.
This leaflet contains concise information about the medicine. If you have any further questions, please refer to your doctor or pharmacist.
Take this medicine according to the instructions in the section on dosage in this leaflet.
Consult with a pharmacist if you need additional information.
Refer to your doctor if your symptoms do not improve after three months of treatment, or if they worsen.

1. What is the medicine intended for?
The medicine is intended for the treatment of premenstrual syndrome (PMS), which includes recurring monthly symptoms prior to menstruation, for women over 18 years of age.

Therapeutic group:
A medicine of herbal origin for the treatment of premenstrual syndrome.

2. Before using the medicine
Do not use this medicine if:

You are sensitive (allergic) to the active ingredient, or to any of the other ingredients this medicine contains (for a list of the other ingredients, please see section 6).

Special warnings regarding the use of this medicine:

Before the treatment with Prefemin tell your doctor if:
- You suffer or have suffered in the past from a tumor (especially prolactin-secreting tumors since the medicine may mask their symptoms; or an estrogen-sensitive cancerous tumor).
- You suffer or have suffered in the past from diseases of the pituitary gland.

Young girls and adolescents:
The medicine is not intended for young girls and adolescent under the age of 18, since there is not enough data on the use in this age group.

Drug interactions:
If you are taking or have recently taken other medicines, including non-prescription medicines and nutritional supplements, inform your doctor or pharmacist.

Especially inform your doctor or pharmacist if you are taking dopamine agonists or antagonists, estrogens or anti-estrogens medicines. If you are not sure whether you are using one of these medicines, consult with your doctor or the pharmacist.

Use of this medicine and food:
This medicine may be taken with or without food.

Pregnancy and breastfeeding:

- Since the medicine is intended to treat premenstrual syndrome, there is no reason to use it during pregnancy.
- Use during breastfeeding is not recommended, since the medicine may affect milk production.

Driving and use of machinery: There is no information regarding possible effects of the medicine on driving or the use of machinery.

Important information on some of the medicine's ingredients:
The medicine contains lactose (see also Section 6). If you have intolerance to some sugars, inform your doctor before taking the medicine.

3. How should this medicine be used?

Check with your doctor or pharmacist if you are not sure regarding the dosage and manner of treatment with the medicine.

The standard dosage is usually: swallow one tablet once a day in the morning with water.
It is recommended to take the tablet at the same time each day.
Do not exceed the recommended dose.
In order to achieve optimal treatment results, the recommended duration of treatment is at least three months.
Refer to your doctor if the symptoms do not improve after three months of treatment, or if they worsen.
Crushing/halving/chewing: there is no information regarding crushing/halving/chewing.

If you have accidentally taken a higher dosage: there is no information on taking an overdose of the medicine. If you have taken an overdose, or if a child has accidentally swallowed the medicine, consult a doctor and bring the package of the medicine with you.

If you have forgotten to take the medicine at the required time: do not take a double-dose in order to make up for the forgotten dose.
Take the next dose at the regular time and consult your doctor or pharmacist.
Do not take medicines in the dark! Check the label and the dose <u>each time</u> you take medicine. Wear glasses if you need them.
If you have any further questions regarding the use of this medicine, consult your doctor or pharmacist.

4. Side effects

Like any medicine, the use of Prefemin may cause side effects in some cases. Do not be alarmed while reading the list of side effects, you may not suffer from any of them.

Stop the treatment and refer to a doctor if a severe allergic reaction appears which may include: swelling of the face, shortness of breath, difficulty swallowing, skin reaction (such as rash, urticaria)

Additional side effects:

Side effects of unknown frequency (effects whose frequency has not yet been determined): Headaches, dizziness, digestive system disorders (such as nausea and abdominal pain), acne, changes and irregular menstrual period.

If a side effect appears, if any of the side effects worsen or if you suffer from a side effect not mentioned in this leaflet, consult with your doctor.

Side effects may be reported to the Ministry of Health by clicking on the link "Report on side effects following medicinal treatment" found on the homepage of the Ministry of Health website (www.health.gov.il) which directs you to the online form for reporting side effects, or by entering the link:
https://sideefects.health.gov.il/

5. How to store the medicine?

- Avoid poisoning! This medicine, and any other medicine, must be stored in a closed place out of the reach and sight of children and/or infants, to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) stated on the package. The expiry date refers to the last day of that month.
- Storage conditions: Store below 25^{O}C.

6. Additional information

- **In addition to the active ingredient, the medicine also contains:**

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

Each tablet contains approximately 40 mg of lactose.

- **What does the medicine look like and what does the package contain?**

White, round, film-coated tablets, convex on both sides .
The tablets come in blister-packs of 30 or 90 tablets in a box. Not all pack sizes may be marketed.

Registration holder: Rafa Laboratories Ltd., P.O.B 405, Jerusalem 9100301.
Manufacturer: Max Zeller Söhne AG, Switzerland**.**

Drug registration number in the National Drug Registry of the Ministry of Health:
164-38-35417
Approved in April 2020.

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