PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

The medicine is dispensed without a doctor's prescription

Prefemin®

Film-coated tablets

Active ingredient:
Each tablet of Prefemin contains: 20 mg agnus castus fruit dry extract (Agni casti fructus).
For the list of the additional ingredients, see section 6.
See also 'Important information about 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 the doctor or pharmacist.
Take the medicine according to the instructions in the dosage section of this leaflet. Consult the pharmacist if you require additional information.
Refer to the doctor if the 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 symptoms recurring monthly before the onset of menstruation, for women from the age of 18 years.

Therapeutic group:

Herbal medicine for the treatment of premenstrual syndrome.

2. Before using the medicine

Do not use the medicine if:

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

Special warnings regarding the use of the medicine:

Before starting treatment with Prefemin tell the doctor if:

- You suffer or have suffered from a tumor (particularly: tumors secreting prolactin as the medicine could hide their symptoms; or an estrogen-sensitive cancer).
- If you are using medicines containing dopamine agonists or antagonists, estrogens or antiestrogens.
- You suffer or have suffered from pituitary gland diseases.

When using the medicine, consult the doctor if:

- The symptoms worsen or do not improve after over three months.

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

Drug interactions:

If you are taking, are planning to begin taking, or have recently taken any other medicines, including non-prescription medicines and nutritional supplements, please tell the doctor or pharmacist.

Particularly inform the doctor or pharmacist if you are taking medicines containing dopamine agonists or antagonists, estrogens or antiestrogens. If you are not sure whether you are using one of these medicines, please consult the doctor or pharmacist.
No studies have been performed on drug interactions and therefore no drug interactions are known to date.

Use of the medicine and food:
The medicine may be taken with or without food.

Pregnancy and breastfeeding:

- Consult the doctor or pharmacist before using the medicine if you are pregnant, are planning a pregnancy or are breastfeeding.
- The medicine is not intended for use during pregnancy. Do not use the medicine if you are pregnant or breastfeeding as there is insufficient information.

Driving and use of machinery: there is no information on the possible effect the medicine may have on driving and use of machinery.

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

3. How to use the medicine?

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

The standard dosage is usually:
Women over the age of 18
Swallow one tablet once a day in the morning with water.
It is recommended to take the tablet at the same time every day.
Do not exceed the recommended dose.
To achieve the optimal treatment results, the recommended duration of treatment is at least three months.
Refer to the doctor if the symptoms do not improve after three months of treatment, or if they worsen.
Crushing/halving/chewing: there is no information on crushing/halving/chewing.

If you accidentally took 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, refer immediately to a doctor or hospital emergency room and bring the package of the medicine with you.

If you forgot to take the medicine at the required time, do not take a double dose to compensate for the forgotten dose.
Take the next dose at the usual time and consult the doctor or pharmacist.
Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.
If you have further questions concerning the use of the medicine, consult the doctor or pharmacist.

4. Side effects

As with any medicine, the use of Prefemin may cause side effects in some users. 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 (e.g. rash, urticaria).

Additional side effects:
Side effects of unknown frequency (effects whose frequency has not yet been determined):
Headaches, dizziness, gastrointestinal disorders (e.g. nausea and abdominal pain), acne, menstrual changes and irregularity.

If a side effect appears, if one of the side effects worsens or if you suffer from a side effect not mentioned in this leaflet, consult the doctor.

Side effects may be reported to the Ministry of Health by clicking on the link "Report on side effects following medicinal treatment" on the homepage of the Ministry of Health website (www.health.gov.il) which leads to an online form for reporting side effects, or by entering the link: https://sideeffects.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 babies, to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the 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°C. Store in the original package in order to protect from moisture.

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 capsule contains approximately 40 mg lactose.

- **What does the medicine look like and what does the pack contain?**
  White, round, convex film-coated tablets.
  The tablets are marketed in blister packs of 30 or 90 tablets per box. Not all pack sizes may be marketed.

Registration Holder: Rafa Laboratories Ltd., PO Box 405, Jerusalem 9100301
Manufacturer: Max Zeller Söhne AG, Switzerland.

Medicine registration number in the National Medicines Registry of the Ministry of Health:
164-38-35417
Revised in April 2024.