Patient leaflet According to the Pharmacists' Regulations (Preparations) - 1986

This medicine is sold with a doctor's prescription only

Cimidona

Tablets

Active ingredient:

Each tablet of Cimidona contains: 6.5 mg of dry extract from Cimicifugae rhizoma (black cohosh).

See section 6 for the list of inactive ingredients.
See also 'Important information about some of the medicine's ingredients' in section 2.

Read the entire leaflet carefully before using this medicine.

This leaflet contains concise information about the medicine. If you have any further questions, contact the doctor or pharmacist.

The medicine is intended for menopausal women.

Contact the doctor if the symptoms worsen or do not improve. See also section 3.

You should use the medicine in the correct manner.

Consult the doctor or pharmacist if you need additional information.

1. What is this medicine intended for?

The medicine is intended for relief of menopause symptoms (hot flushes, excessive sweating, sleep disorders, nervousness and depressive moods).

Therapeutic group:
A medicine from an herbal source for relief of menopause symptoms.

2. Before using this medicine

Do not use this medicine if:

Do not use if you are sensitive (allergic) to the active ingredient, to plants of the Ranunculaceae family or to any of the other ingredients this medicine contains (see section 6 for the list of inactive ingredients).

Special warnings regarding the use of this medicine:

- **The treatment is not recommended** in cases of existing liver damage. Abnormal fatigue, weakness, loss of appetite, weight loss, yellowing of the skin or the conjunctiva, dark urine and pale stool may be signs of liver damage. If these symptoms appear, stop the treatment with the medicine and contact the doctor.
- **Before the treatment with this medicine, tell the doctor or the pharmacist if** you suffer from other diseases or any allergy.
- **Consult the doctor if** you feel swelling or tightness in the breasts, or if you experience intermenstrual bleeding, spotting or recurrence of menstrual periods.
- The medicine is not intended as a preventative treatment for osteoporosis (bone dwindling).
- **If you are taking or have recently taken any other medicines, including non-prescription medicines and nutrition supplements, please tell your doctor or pharmacist.**

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

Pregnancy and breastfeeding:
The medicine is intended for use by menopausal women and is not intended for use by pregnant or breastfeeding women.

Use in children:
The medicine is not intended for children**.**

Important information about some of the medicine's ingredients:
- The medicine contains lactose. If you are sensitive to lactose, inform the doctor before taking this medicine (see section 6).
- Information for diabetes patients: the tablet contains 0.004 carbohydrate exchange unit.

3. How should you use the medicine?

Always use according to doctor's instructions. Check with the doctor or pharmacist if you are not sure.
The dosage and the manner of treatment will be determined by the doctor only.
The standard dosage is usually: one tablet once a day.
The recommended treatment duration is at least 6 weeks, and it may be used for several months. Usage for more than 6 months should be only after consulting the doctor.
It is recommended to take the tablet at the same time every day. Swallow the tablet whole.
Do not exceed the recommended dose.
Do not crush, chew or halve the tablet.
If you think that the effect of the medicine is too weak or too strong – consult the doctor or the pharmacist.

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

If you forgot to take the medicine at the scheduled time, do not take two doses together.

Continue with the treatment as recommended by the doctor.
Do not take medicines in the dark! Check the label and the dose <u>each time</u> you take a medicine. Wear glasses if you need them.
If you have any further questions regarding the use of this medicine, consult the doctor or the pharmacist.

4. Side effects

Like any medicine, the use of Cimidona 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 contact the doctor if you experience symptoms which may indicate damage to the liver (very rare).
These symptoms include: yellowing of the skin and/or eyes, dark urine, pale stool, increased weakness and abnormal fatigue, loss of appetite, unplanned weight loss.

Additional side effects:

Side effects which appear rarely:
Nausea, mild abdominal pain.
Spotting, unusual bleeding, recurrence of menstrual bleeding, swelling or tightness in the breasts. See also 'Special warnings regarding the use of this medicine'.

If a side effect has appeared, or if any of the side effects is persistent, worsening or bothersome, if you experience any side effects not listed in this leaflet, or if any change has occurred in your general feeling, you should consult the doctor.

5. **How to store the medicine?**

- Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the reach of children and/or infants in order to prevent 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.

6. **Additional information**

In addition to the active ingredient, the medicine also contains the following inactive ingredients:

Povidone, cellulose microcrystalline, lactose monohydrate, croscarmellose sodium, magnesium stearate, silica colloidal anhydrous.

Each tablet contains about 44 mg lactose.

What does the medicine look like and what does the package contain?
Round yellow – beige tablets.
The tablets are packed in blisters, in packs of 30 or 90 tablets per box.

Registration holder: Rafa Laboratories Ltd., P.O. Box 405, Jerusalem 9100301
Manufacturer: Max Zeller Söhne AG, Switzerland.
Medicine registration number in the National Medicine Registry of the Ministry of Health: 1538834027

This leaflet was checked and approved by the Ministry of Health in May 2015.