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

The medicine is dispensed without a doctor's prescription

Cimidona® 6.5 mg

Tablets

Active ingredient:

Each tablet of Cimidona 6.5 mg contains: dry extract from Cimicifugae Rhizoma (Black Cohosh) 6.5 mg

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.

Use this 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 illness symptoms worsen or do not improve after 6 weeks (see also section 3).

1. What is the medicine intended for?

The medicine is intended to relieve menopausal effects (hot flashes, excessive perspiration, sleep disorders, nervousness and depressive moods).

Therapeutic Group:
Gynecological drugs

2. Before using the medicine

Do not use the medicine if:

- You are sensitive (allergic) to the active ingredient, plants of the buttercup family (ranunculaceae) or to any of the additional ingredients the medicine contains (for a list of the additional ingredients, see section 6).
- If you suffer or suffered in the past from liver functions disorder.

Special warnings regarding the use of the medicine:

- Discontinue use of the medicine and refer to a doctor immediately if symptoms that may indicate liver injury develop (abnormal fatigue, lack of appetite, weight loss, yellow coloration of the skin and/or eyes, severe upper abdominal pain accompanied by nausea and vomiting, diarrhea, dark urine or discolored stool).

- **Liver functions monitoring will be performed according to a doctor's instructions.** See also "Tests and monitoring" and "Side effects".

Before starting treatment with the medicine, tell the doctor if:

- You suffer from other illnesses or if you suffer from any allergy.

• **Consult the doctor if** you experience swelling or tension in the breasts, or if you experience intracycle bleeding, spotting or recurring of your period.
• The medicine is not intended for preventative treatment of osteoporosis.

Children and adolescents:
The medication is not intended for children and adolescents.

Tests and monitoring: Liver functions monitoring will be performed according to doctor's instructions.

Drug interactions:
If you are taking, or have recently taken any other medicines, including non-prescription medicines and nutritional supplements, please tell the doctor or pharmacist. There are no known drug interactions with use of this medicine.

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

Pregnancy and breastfeeding:
The medicine is intended for menopausal women and is not intended for pregnant or breastfeeding women. There is no information on the use of the medicine during pregnancy and lactation.

Driving and use of machinery:
There is no information regarding the effect of the medicine on the ability to drive or operate machinery.

Important information about some of the medicine's ingredients:
The medicine contains lactose. If you have intolerance to certain sugars, tell your doctor before taking this medicine.
Each tablet contains less than 1 mmol sodium (23 mg), namely it is considered "sodium-free".

3. How to use this medicine?

You should check with the doctor or pharmacist if you are not sure regarding the dosage and manner of treatment.
The standard dosage is usually: one tablet once a day.
It is recommended to take the tablet at the same time every day. The tablet should be swallowed whole with water.
Do not exceed the recommended dose.
The effect of the medicine is not immediate. The recommended duration of treatment is at least 6 weeks, and it can be used for a number of months. Do not use for a period of more than 6 months without consulting a doctor.
There is no information regarding crushing/chewing/halving the tablet.
If you think the effect of the medicine is too weak or too strong - consult the doctor or pharmacist.

If you accidentally took a higher dosage: There is no information regarding 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 medicine package with you.

If you forgot to take the medicine at the required time, do not take a double dose**.**

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

Like any medicine, the use may cause side effects in some users. Do not be alarmed by the list of side effects. You may not suffer from any of them.

Stop the treatment and refer to a doctor if you experience symptoms that may indicate liver injury, such as impairment of liver functions (can be seen in tests), jaundice, liver inflammation. These symptoms can include: abnormal decrease in activity, abnormal fatigue, increased weakness, loss of appetite, unintended weight loss, jaundice (yellowing of the skin and/or conjunctiva), severe upper abdominal pain with nausea and vomiting, dark urine, discoloration of stool.

Additional side effects:

Rare side effects (appear in 1-10 users out of 10,000):

- Gastrointestinal problems such as: nausea, abdominal pain, heartburn, diarrhea.
- Spotting, intracycle bleeding, recurring of the period, swelling or tension in the breasts. See also “Special warnings regarding the use of the medicine”.

Side effects of unknown frequency (effects whose frequency has not yet been determined):

- Skin reactions such as rash, itching, urticaria.
- Edema in the face and/or body.

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) that leads to the 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 in the original package.

6. Additional information

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

Cellulose, microcrystalline; lactose monohydrate (44 mg); croscarmellose sodium; povidone; magnesium stearate; silica, colloidal anhydrous.

What does the medicine look like and what does the package contain?
Round tablets, colored yellow-beige (sometimes brown specks deriving from the active ingredient appear). There is no score line on the tablets.

The tablets are packed in blisters, in packs of 30 or 90 tablets per box.
Not all pack sizes may be marketed.

Registration Holder: Rafa Laboratories Ltd., P.O. Box 405, Jerusalem 9100301.

Manufacturer: Max Zeller Söhne AG, Switzerland.

Medicine registration number in the National Medicines Registry of the Ministry of Health: 153-88-34027

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