Patient Leaflet According to the Pharmacists' Regulations (Preparations) – 1986
This medicine is sold with a doctor's prescription only

Cimidona Forte 13 mg
Tablets

Active ingredient:

Each tablet of Cimidona Forte 13 mg contains:
Dry extract from cimicifugae rhizoma (black cohosh) 13 mg

For a list of other ingredients see section 6.
See also 'Important information about some of the medicine's ingredients' in section 2.

Read this 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.
This medicine has been prescribed for treatment for you. Do not pass it on to others. It may harm them, even if you think their medical condition is similar to yours.

1. What is the medicine intended for?

The medicine is intended to relieve menopausal symptoms (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 substance, plants of the buttercup family (ranunculaceae) or any of the other ingredients that the medicine contains (for a list of the other ingredients, see section 6).
- If you suffer or suffered in the past from liver disorder.

Special warnings regarding the use of this medicine:

- Discontinue use of the medicine and seek medical attention immediately if you develop symptoms that may indicate liver injury (abnormal fatigue, lack of appetite, weight loss, yellow coloration of the skin and/or eyes, severe epigastric pain accompanied by nausea and vomiting, diarrhea or dark urine).
- **Liver functions monitoring will be performed in accordance with the instructions of the attending doctor.** See also “Tests and monitoring” and “Side effects”.

Before starting treatment with the medicine, tell your doctor if:
- You have any other medical conditions or any allergy.
- **Consult your doctor if** you experience a feeling of swelling and tension in the breasts, or if you experience intracycle bleeding, spotting or recurring of your period.
- This medicine is not intended for prophylactic treatment of osteoporosis .

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

Tests and monitoring: Liver functions monitoring will be performed in accordance with the instructions of the attending doctor.

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

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

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

Driving and use of machinery:
No information is available regarding the effect of the product on the ability to drive or operate machinery.

Important information about some of the medicine's ingredients:
The medicine contains about lactose. If you have intolerance to certain types of 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?

Always use according to the doctor's instructions. You should check with your doctor or pharmacist if you are not sure regarding the dosage and the manner of treatment with the medicine.
The dosage and the treatment manner should be determined by the doctor only.

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 in whole with water.
Do not exceed the recommended dose.
The recommended duration of treatment is 6 weeks at least, and it can be continued for several months. Do not use for a period of more than 6 months without consulting a doctor.
No information available on crushing / chewing / halving the tablet.
If you think the effect of the medicine is too weak or too strong - consult your doctor or pharmacist.

If you accidentally took a higher dosage: There is no available information on medicine overdosing. If you have taken an overdose or if a child has accidentally swallowed the medicine, immediately turn 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**.**

Adhere to the treatment regimen recommended by your doctor.

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 of the medicine 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 the doctor If you experience symptoms that may indicate liver injury, such as disturbance of liver function (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 or the conjunctiva), severe upper abdominal pain with nausea and vomiting, dark urine, discoloration of stool.

Additional side effects include:

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

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

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

- Skin reactions such as rash, itching, urticaria.
- Water retention 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 your 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 directs you 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 infants, 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 in the original package below 25°C.

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?
Cimidona Forte 13 mg: Round tablets, yellow-beige, with embossment (sometimes brown specks deriving from the active ingredient appear). There is no score line on the tablets.
The tablets are packed in blisters and are available 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:
Cimidona Forte 13 mg: 163-70-35388

Revised in November 2021 according to MOH guidelines.

155002-MZ