Product characteristics

Name of Product

Cimidona

Composition

Active substance: Dry extract, , from Cimicifugae rhizoma (Black cohosh)

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

Information for diabetics : 1 tablet contains 0.004 carbohydrate exchange units.

The product contains lactose (44 mg per tablet).

Galenic Form and Active Substance per Unit:

Tablet.

6.5 mg dry extract (Ze 450) from Cimicifugae rhizoma der 4.5 – 8.5:1, extraction solvent 60% ethanol (V/V).

Indications:

For the alleviation of complaints during menopause (hot flashes, excessive perspiration, sleep disorders, nervousness and depressive moods).

Dosage :

1 tablet to be taken once daily, unchewed, with some fluid, preferably always at the same time of the day (in the morning or in the evening). The intake of the tablets does not depend on meals.

The effect does not set in immediately. Intake of Cimidona is recommended for a period of at least 6 weeks.

It is recommended to take Cimidona over several months; however, it should not be applied for more than 6 months without medical advice.

Contraindications:

Cimidona must not be taken in cases of existing hypersensitivity to one of its ingredients or to any plants of the Ranunculaceae (butter cup) family.

Special Warnings and Precautions:

- The intake of Cimidona is not advised in cases of pre-existing liver damage. This preparation has an effect on physical and psychological complaints during the menopause. Since there is no clinical data so far with regard to a positive effect on bones, this preparation can therefore not be used for the prevention of osteoporosis.
- Unusual fatigue, weakness or loss of appetite and unintended weight loss, yellow colouring of the conjunctiva or the skin, dark urine, or discolouration of stool can be an indication of liver damage. If such symptoms occur, Cimidona must be discontinued and a physician must be consulted.
- A physician should be consulted in the event of a sensation of tension or swelling in the breasts or if irregular bleeding, spotting, or recurrence of menstrual bleeding occurs.

Interactions:

None known.

Pregnancy, Lactation:

The use of preparations containing Cimicifugae racemosae rhizoma is indicated for

menopausal women. Administration during pregnancy and lactation is not intended.

Effect on the Ability to Drive and Operate Machines:

No relevant studies have been performed.

Adverse Events:

Evaluation of adverse events is based on the following incidence reports:

Very frequent: ≥ 1/10

Frequent: ≥ 1/100 to < 1/10

Occasional: ≥ 1/1,000 to < 1/100

Rare: ≥ 1/10,000 to < 1/1,000

Very rare: < 1/10,000

Gastrointestinal dysfunction: In rare cases, slight gastric complaints and nausea can occur.

Liver and bile: In single cases, there is evidence for partly severe liver damage.

Endocrine disorders: Spotting and irregular bleeding as well as recurrence of menstrual bleeding can be observed in individual cases.

See also “Special Warnings and Precautions”.

Overdose:

No cases of overdose were reported.

Characteristics / Effects:

ATC-Code

G02CX

Mode of Action / Pharmacodynamics:

Ethanolic extracts of the Cimicifuga rhizome contain triterpene glycosides, flavone derivatives and aromatic acids.

The effect of Cimicifuga extracts on human oestrogen receptor-positive and receptor-

negative breast cancer cell lines was tested in different in-vitro experiments. The results are equivocal. The majority of published studies, among others a study with Cimicifuga extract Ze 450, could show an inhibition of proliferation, or no cell proliferation.

In a clinical trial with 400 postmenopausal women, the thickness of the endometrium was determined by vaginal ultrasound. Over a time period of one year, no increase in endometrial thickness was observed. Also, hormonal parameters (LH, FSH, oestradiol and prolactin) remained unchanged.

This data indicates that the observed Cimicifuga extract effects do not seem to directly affect these hormonal parameters. It could be shown that the substances contained in the Cimicifuga extract have a certain binding affinity to the oestrogen receptor, but lack an oestrogenic effect.

Clinical Efficacy:

The efficacy of Cimidona for the treatment of climacteric complaints was examined in a prospective, placebo-controlled, dose-dependent, randomised clinical study.
In this 3-arm study, the superiority of Cimidona as compared to placebo was demonstrated over a time period of 12 weeks. The primary target variable, the Kupperman index, showed a dose-dependent efficacy in the intent-to-treat collective (N = 153). Women treated for menopausal complaints, for whom a dosage of 6.5 mg is not sufficient, can be successfully treated with 13 mg dose.

Pharmacokinetics:

So far, no pharmacokinetic studies were conducted for the galenic formulation present in Cimidona.

Pre-clinical Data:

In a toxicity study with rats with repeated oral administration of Cimicifuga dry extract (Ze 450) over a period of 7 days, no toxic reactions could be found in histological or microscopic examinations either.

The salmonella microsome assay according to Ames did not reveal any indication of a mutagenic effect of the dry extract Ze 450 from *Cimicifuga racemosa* (black cohosh) rhizome.

There is no knowledge on reproduction toxicology and carcinogenicity.

Additional Information:

Incompatibilities

Not applicable.

Influence on diagnostic methods

Not known.

Special instructions for storage

Store below 25 °C.

The medication is to be kept out of the reach of children.

Packages:

Cimidona tablets 30

Cimidona tablets 90

MANUFACTURER

MAX Zeller Sohne AG, Seeblickstrasse 4, ch-8590 Romanshorn, Switzerland

REGISTRATION HOLDER

Rafa Laboratories Ltd., P.O.Box 405, Jerusalem 9100301, Israel

Drug registration number: 153 88 34027

The format of this leaflet was determined by the Ministry of Health and its content was checked and approved by it in May 2015.