

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Klimaktoplan

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 tablet (250 mg) contains:

Active substances:

Cimicifuga trit. D2	25.00 mg
Ignatia trit. D3	25.00 mg
Sepia trit. D2	25.00 mg
Sanguinaria trit. D6	25.00 mg

Excipients with known effect: lactose monohydrate, wheat starch
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablet

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Conditions arising during menopause such as hot flushes, sweating, rapid heartbeats (palpitation), vertigo, itching, inner restlessness, sleep disturbances, depressive mood and nervous irritability.

4.2 Posology and method of administration

Posology

Initially, 1-2 tablets are taken 3 times per day. When complaints improve, the dosage should be reduced.

Method of administration

Tablets should be allowed to dissolve slowly in the mouth. If necessary, tablets can be dissolved in a little bit of water.

An interval of at least half an hour to meals should be kept.

4.3 Contraindications

Hypersensitivity to the active substances or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

This medicinal product contains lactose and wheat starch. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicinal product. Wheat starch may contain gluten, but only in trace amounts, and is therefore considered safe for people with coeliac disease. Patients with wheat allergy (different from coeliac disease) should not take this medicinal product.

A reassessment of the therapy is necessary
- if condition does not improve or worsens,
- if additional complaints arise.

4.5 Interaction with other medicinal products and other forms of interaction

Interactions with other medicinal products have not been observed. The use of this homeopathic medicinal product does not exclude the use of other medicinal products.

Patients are advised to consult a doctor if they are taking, have recently taken or might take any other medicinal products.

Note: The action of homeopathic medicinal products may be adversely affected by generally negative factors of living habits as well as by stimulants or drink and tobacco.

4.6 Pregnancy and lactation

Klimaktoplan is not indicated during pregnancy and lactation.

4.7 Effects on ability to drive and use machines

Klimaktoplan has no influence on the ability to drive and use machines.

4.8 Undesirable effects

Very rare (< 1/10,000) or not known (frequency cannot be estimated from the available data): Hypersensitivity reactions may appear. Nosebleed may occur and menstrual bleedings may reoccur or become more frequent. In these cases, Klimaktoplan should be discontinued and appropriate treatment measures have to be taken.

Note: Existing complaints may temporarily become worse when homeopathic medicines are taken (initial homeopathic aggravation). In such cases, patients are advised to discontinue the medication and consult a doctor.

4.9 Overdose

No case of overdose has been reported.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Homeopathic medicinal product.

Homeopathic therapy differs markedly from conventional medicine with regard to the understanding of disease and the use of medicinal substances. Homeopathic remedies stimulate the organism's own defense mechanisms and thereby activate its self-healing power. The response of the organism to a homeopathic remedy is highly individual. For these reasons dose-specific pharmacological effects, pharmacodynamic or pharmacokinetic data can not be determined.

5.1 Pharmacodynamic properties

Not applicable.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

Not applicable. Klimaktoplan as a homeopathic pharmaceutical has not gone through preclinical testing.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate, magnesium stearate, wheat starch.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

5 years.

Do not use after the expiration date indicated on the package.

6.4 Special precautions for storage

Store at a temperature not exceeding 25 ° C. Store out of reach and sight of children.

6.5 Nature and contents of container

20 tablets in blister. Package containing 3 blisters and PIL.

6.6 Special precautions for disposal

No special requirements.

7. MANUFACTURER

Dr. Gustav Klein GmbH & Co. KG
Steinenfeld 3, 77736 Zell am Harmersbach, Germany
Telephone: +49 (0) 7835 635530
www.klein-naturarznei.de

8. MARKETING AUTHORISATION HOLDER

Alpen Pharma GmbH, Steinenfeld 3,
77736 Zell am Harmersbach, Germany
Telephone: +49 (0) 7243 200 49 10
www.alpenpharma.com

9. MARKETING AUTHORISATION NUMBER(S)

[To be completed]

10. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

13/05/2005

11. DATE OF REVISION OF THE TEXT

May 2024



i. A. Perian