

SUMMARY OF PRODUCT CHARACTERISTICS

1. TRADE NAME OF THE MEDICINAL PRODUCT

KLIMALANIN, tablet

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Beta-alanine 400.00 mg

Excipients :

Magnesium stearate	8.00 mg
Glycerol palmityl stearate	31.20 mg
Hydrated silica	36.00 mg
Wheat starch	304.80 mg

For a 780.00 mg tablet

3. PHARMACEUTICAL FORM

Tablet.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Used in hot flushes related to menopause.

4.2 Posology and mode of administration

Oral route

The posology is 1 to 2 tablets daily. This dose can be increased without any inconvenience to 3 tablets per day.

Drug should be administered during a 5 to 10 day period until hot flushes disappear.

On recurrence of the latter, a new drug treatment becomes necessary during the same period.

As no addiction has been observed, the treatment can be extended on the whole period of vasomotor clinical disorders without limitation of its duration.

4.3 Contra-indications

- Hypersensitivity to beta alanine or to one of the excipients.
- Hypersensitivity or intolerance with gluten, because of the presence of wheat starch (gluten).

4.4 Special warnings and special precautions for use

In case of persistent symptoms, worsening or appearance of new troubles, the treatment has to be reassessed.

In case of cutaneous side effects (rash, pruritus) the treatment has to be stopped.

Treatment by beta-alanine does not dispense with any additional specific treatment.

4.5 Interaction with other drugs and other forms of interaction

4.6 Pregnancy and lactation

KLIMALANIN 400 mg is indicated in menopausal women.

Pregnancy

Clinical or animal data are insufficient to expect a potential risk of KLIMALANIN 400 mg causing malformation or foetotoxicity.

Breast-feeding

There are no available data concerning the passage into breast milk of KLIMALANIN 400 mg.

4.7 Effects on ability to drive and use machines

4.8 Undesirable effects

Rarely : transitory pins and needles most often in the extremities of the upper and lower limbs.
Exceptionally: skin rash or itching.

4.9 Overdose

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC code: G02CX Other gynecologicals

Beta-alanine, pure aminoacid, remedies against peripheral vasodilatation phenomena as non-hormonal inhibitor of hot flushes due to menopause.

5.2 Pharmacokinetic properties

5.3 Preclinical safety data

6. PHARMACEUTICAL PROPERTIES

6.1 Incompatibilities

6.2 Shelf life

3 years.

6.3 Special precautions for storage

Store at temperature below 25°C.

6.4 Nature and contents of containers

PVC film coated by an aluminium foil. Cardboard box containing 30 tablets in 2 blisters of 15 tablets or 30 tablets in 3 blisters of 10 tablets

6.5 Instructions for use and handling

7. MARKETING AUTHORIZATION HOLDER

BOUCHARA-RECORDATI
70 Avenue Général de Gaulle
92 800 PUTEAUX - France

Manufacturer

Laboratoires BOUCHARA-RECORDATI
Parc Mécatronic
03 410 SAINT VICTOR - France

8. MARKETING AUTHORIZATION NUMBER

French Marketing Authorization n°: 335 289.2