

CLIMAVIT®

The menopause is the physiologic situation which establishes in the woman aged around 50 years and that is due to the reduced production of oestrogen hormones.

At the beginning, the oestrogen deficiency causes the onset of symptoms such flushing, nocturnal sweating, palpitations, insomnia, irritability, anxiety and mood alterations, vaginal dryness, and progressively a loss of minerals constituting bones with risk of osteoporosis, atrophy of genito-urinary tissues and skin aging.

The climacteric symptoms should be considered not only as troubles limited to a worse quality of life, but also as osteoporotic and cardiovascular (CV) risk factors and cerebral deterioration. In fact, the most severe flushing are correlated with quick osseous loss and osteoporosis⁽¹⁾, poorest verbal memory⁽²⁾, low levels of plasmatic antioxidant activity, increased CV reactivity to stress, altered flow mediated dilation⁽¹⁾, systolic blood pressure⁽³⁾.

Furthermore, vasomotor symptoms (flushing and nocturnal sweating) are associated to an increased risk of coronary heart diseases, that cannot be totally explained by the levels of the CV risk factors.⁽⁴⁾

CLIMAVIT® balances the hormonal deficiencies of the menopause and peri-menopause, it can be used in opposing the typical vasomotor troubles of the menopause, it is adaptogenic against psychic and physical stress, it controls the anxious symptoms and depressed mood and it improves the quality of sleep, as integration of an adequate and varied diet.

SOLUBLE TECHNOLOGY

Soluble formulations are solide immediate release forms that need to be dissolved in water with rapid stirring at the time of administration. They yield an oral solution or suspension depending on API solubility.

- **Fast onset of action**
- **Large amount of API**
- **High bioavailability**
- **Easy to manage than conventional liquids**
- **User friendly**
- **Solvent and alcohol free**

ODG TECHNOLOGY

Designed to disintegrate rapidly on contact with saliva and enable oral administration without water or chewing. This kind of formulation offer increased convenience and ease of administration with the potential to improve compliance, particularly in certain populations where swallowing conventional solid oral-dosage forms is difficult.

- **No water**
- **Fast onset of action**
- **Quick dissolution**
- **Excellent mouth feel**
- **Patience compliance (geriatric and pediatric population)**
- **User friendly**
- **Solvent and alcohol free**

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CLIMAVIT®
FOOD SUPPLEMENT

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Food supplement for the Menopause based on Genistein, Agnus castus and Hawthorn extracts, Vitamin D3 and Calcium

Genistein (soy isoflavon) has a recognised activity on vasomotor symptoms, Agnus castus is active on flushing and psychological symptoms and Hawthorn on psychoaffective symptoms, particularly anxiety, irritability and mood.

Vitamin D3 and Calcium favour the trophism and the mineralisation of osseous tissue.



CLINICAL DATA

Efficacy and safety of **CLIMAVIT®** have been under evaluation in a preliminary, observational, clinical study, in which menopause women presenting more than 5 moderate flushing per day concomitantly with an anxious state or sleep disorders, not so severe to require pharmacologic therapy, were recruited.

The women on treatment with hormonal replacement therapy or other products taken for the relief of symptoms under evaluation, were excluded. (De Leo et al. 2017).

CLIMAVIT® is administered orally at the dose of 1 sachet/day for at least 12 weeks.

At baseline, after 6 and 12 weeks from start of the treatment, the Kupperman Index is calculated considering the severity of flushing, nocturnal sweating, insomnia, irritability, depressed mood or melancholia, dizziness, fatigue, muscular and articular pain, headache, palpitations and paresthesias.

Vaginal dryness, dyspareunia, anxiety and libido loss are determined at start and the end of the treatment.

Phytosurveillance: any adverse reaction or unwanted event is recorded in the Case report form, specifying severity, duration, onset time, relationship with the treatment and the action taken.

INDICATIONS

CLIMAVIT® is a food supplement, available as orally disintegrating granules (in stick) and soluble granules (in sachet), for the wellness of the woman in menopause and in case of increased need of minerals or decreased intake with the diet.

CLIMAVIT® exploits the synergy of Genistein, Vitex Agnus Castus and Hawthorn to help hot flushing and nocturnal sweating mitigation as well as night time sleep quality.

HOW TO USE

1 sachet or stick per day is recommended. The odg should be dissolved directly in the mouth. The soluble granules should be dissolved in a glass of water.

- GLUTEN FREE
- LACTOSE FREE
- SUGAR FREE
- PRESERVATIVES FREE



INGREDIENTS

	Content for sachet/stick	% RNV*
GENISTEIN (isoflavon)	80 mg	
AGNUS CASTUS (<i>Vitex agnus-castus L., fruits</i>) dry extract	40 mg	
HAWTHORN (<i>Crataegus oxyacantha auct.,</i> leaf and flowers) dry extract (min. 1.8% vitexin)	300 mg	
Vitamin D3	5 µg	100 %
Calcium**	240 mg	30 %

(*) % Reference Nutrient Values - (**) for ODG Calcium content is 120mg (%RNV 15%)

BIBLIOGRAPHY

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- ⁽³⁾ Gerber LM, Sievert LL, Warren K, Pickering TG, Schwartz JE. *Hot flashes are associated with increased ambulatory systolic blood pressure.* Menopause, 2007;14 (2):308-15.
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